Volume III of IX (Appx23131-Appx27244) No. 2024-1285

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

APPLE INC.,

Appellant,

ν.

INTERNATIONAL TRADE COMMISSION,

Appellee,

MASIMO CORPORATION, CERCACOR LABORATORIES, INC.,

Intervenors,

On Appeal from the United States International Trade Commission in Investigation No. 337-TA-1276

NON-CONFIDENTIAL JOINT APPENDIX

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CERTIFICATE OF SERVICE

CONFIDENTIAL MATERIAL OMITTED

The material omitted from Appx9; Appx36; Appx41-44; Appx46-48; Appx108; Appx119; Appx121-122; Appx150-151; Appx153-154; Appx156-158; Appx187-190; Appx192-194; Appx196; Appx198; Appx218; Appx220-222; Appx265-276; Appx373; Appx13067-13069; Appx21846; Appx22790; Appx22954; Appx22956-22958; Appx22985; Appx22990; Appx23139; Appx23166; Appx23171-23174; Appx23238; Appx23249; Appx23251-23252; Appx23280-23281; Appx23283-23284; Appx23286-23288; Appx23317-23320; Appx23322-Appx23323; Appx23326; Appx23328; Appx23348; Appx23350-23352; Appx23395-23406; Appx23656; Appx23658; Appx23681-23682; 23688; Appx23791; Appx24147-24148; Appx40795-40798; Appx40996-40999; Appx41019-41026; Appx41029-41030; Appx41058-41062; Appx41077-41080; Appx41094-41097; Appx41108-41110; Appx51900-51924; Appx52602-52606; Appx52609; Appx52642-52645; Appx52791-52795; Appx52822-52824; Appx52911-52912; Appx52939-52941; Appx52980-52982; Appx53016-53019; Appx60425-60431; Appx60432-60434; Appx70322-70355; Appx70774; Appx70781-70783; and Appx70841-70876 contains Apple's confidential competitively sensitive product information subject to the Administrative Protective Order; the material omitted from Appx4579 and Appx53459-53461 contains competitively sensitive information regarding confidential agreements; the material omitted from Appx23439; Appx23441-23446; Appx23448; Appx23450-23453; Appx23455-23458; Appx23462; Appx23617; Appx23621; Appx23659-23665; Appx25251; Appx40483; Appx40582-40584; Appx40600-40601; Appx40605; Appx40652-40655; Appx40658-40662; Appx53491; Appx53492; Appx53497; Appx53499; Appx53503; Appx53506; Appx65064-65075; Appx65075; Appx65104-65105; Appx65315; Appx65321-65232; and Appx71223-71244 contains Masimo's confidential competitively sensitive financial information subject to the Administrative Protective Order; the material omitted from Appx311-316; Appx23667-23674; Appx40579-40581; Appx40585-40599; Appx40602-40604; Appx40610-40614; and Appx40631-40633 contains Masimo's confidential competitively sensitive financial and manufacturing information subject to the Administrative Protective Order; the material omitted from Appx473-474; Appx62; and Appx23176-23178 contains Masimo's confidential competitively sensitive manufacturing information subject to the Administrative Protective Order; the material omitted from Appx13047; Appx14129-14140; Appx205-206; Appx211; Appx21848; Appx22282-22286; Appx23197; Appx23204; Appx23335-23336; Appx23341; Appx23408-23416; Appx23434-23436; Appx23454; Appx23642; Appx23644-23645; Appx23647-23649; Appx23685-23687; Appx23693-23697; Appx23704; Appx25253-25260; Appx278-286; Appx2809-

2852; Appx2923-2937; Appx304-306; Appx309; Appx3708; Appx3710-3711; Appx3718; Appx3722; Appx3725; Appx3727; Appx3732; Appx3733; Appx3735; Appx40229-40232; Appx40346-40371; Appx40407-40422; Appx40431-40434; Appx40438-40442; Appx40486-40494; Appx40495-40506; Appx40512-40521; Appx40525-40528; Appx40547-40555; Appx40560- 40574; Appx40803-40822; Appx41217-41221; Appx41350-41356; Appx53070-53095; Appx53107-53151; Appx53222-53234; Appx53236-53252; Appx53256-53361; Appx53362-53365; Appx53813-53838; Appx53927-53941; Appx54064-54226; Appx54227-54266; Appx55229-55354; Appx55359-55376; Appx55386-55399; Appx57317-57324; Appx57394--57409; Appx57410-57412; Appx57615-57618; Appx60136-60153; Appx60184-60212; Appx65014-65019; Appx65022-65025; Appx65028-65037; Appx65040-65074; Appx65207; Appx65224; Appx65267-65268; Appx67; Appx6701-6703; Appx6705; Appx6732-6736; Appx6852-6854; Appx6937-6950; Appx70475; Appx70484-70491; Appx70504-70513; Appx70518-70559; Appx70610-70613; Appx70615-70617; Appx70619-70628; Appx70833-70835; Appx70948-70950; Appx70955-70956; and Appx74 contains Masimo's confidential competitively sensitive product information subject to the Administrative Protective Order; the material omitted from Appx23707-23709; Appx318; Appx320-328; Appx40634; and Appx70592-70594 contains Masimo's confidential competitively sensitive product and financial information subject to the Administrative Protective Order; the material omitted from Appx176; Appx179; Appx22788-22789; and Appx22791 contains Masimo's confidential information detailing non-public patent prosecution subject to the Administrative Protective Order; the material omitted from Appx404-405; Appx457; Appx460-461; Appx464; Appx24103-24104; Appx25387; and Appx25389 contains Apple's confidential competitively sensitive financial and sales information subject to the Administrative Protective Order; the material omitted from Appx52602-52608 contains confidential competitively sensitive product of a third party.

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UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of

CERTAIN LIGHT-BASED
PHYSIOLOGICAL MEASUREMENT
DEVICES AND COMPONENTS THEREOF

Inv. No. 337-TA-1276

FINAL INITIAL DETERMINATION ON VIOLATION OF SECTION 337

Administrative Law Judge Monica Bhattacharyya

(January 10, 2023)

Appearances:

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For Respondent Apple Inc.:

Mark D. Selwyn of Wilmer Cutler Pickering Hale and Dorr LLP in Palo Alto, CA; Joseph J. Mueller, Richard Goldenberg, and Sarah R. Frazier of Wilmer Cutler Pickering Hale and Dorr LLP in Boston, MA; and Michael D. Esch and David Cavanaugh of Wilmer Cutler Pickering Hale and Dorr LLP in Washington, DC.

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Pursuant to the Notice of Investigation (EDIS Doc. ID 749538), 86 Fed. Reg. 46275-76 (Aug. 18, 2021), and Commission Rule 210.42, this is the administrative law judge's final initial determination on violation in the matter of *Certain Light-Based Physiological Measurement Devices and Components Thereof,* Commission Investigation No. 337-TA-1276. 19 C.F.R. § 210.42(a)(1)(i).

For the reasons discussed herein, it is the undersigned's final initial determination that there has been a violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, in the importation into the United States, the sale for importation, and/or the sale within the United States after importation of certain wearable electronic devices with light-based pulse oximetry functionality and components thereof by reason of infringement of certain claims of U.S. Patent No. 10,945,648.

It is also the undersigned's final initial determination that there has been no violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, in the importation into the United States, the sale for importation, and/or the sale within the United States after importation of certain wearable electronic devices with light-based pulse oximetry functionality and components thereof with respect to U.S. Patent Nos. 10,912,501, U.S. Patent No. 10,687,745, and U.S. Patent No. 7,761,127.

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The following abbreviations may be used in this Initial Determination:

Tr.	Hearing Transcript
Dep. Tr.	Deposition Transcript
JX	Joint Exhibit
CX	Complainants' exhibit
CPX	Complainants' physical exhibit
CDX	Complainants' demonstrative exhibit
RX	Respondents' exhibit
RPX	Respondents' physical exhibit
RDX	Respondents' demonstrative exhibit
CPHB	Complainants' pre-hearing brief (EDIS Doc. ID 770786)
CIB	Complainants' corrected initial post-hearing brief (EDIS Doc. ID 775422)
CRB	Complainants' post-hearing reply brief (EDIS Doc. ID 775058)
RPHB	Respondents' corrected pre-hearing brief (EDIS Doc. ID 770874)
RIB	Respondents' second corrected initial post-hearing brief (EDIS Doc. ID 779376)
RRB	Respondents' corrected post-hearing reply brief (EDIS Doc. ID 779379)

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I. BACKGROUND

A. Procedural History

The Commission instituted this investigation in response to a complaint filed by Complainants Masimo Corporation and Cercacor Laboratories, Inc. on June 30, 2021, with an amended complaint filed on July 12, 2021 (the "Amended Complaint," EDIS Doc. ID 746186), and supplemented on July 19, 2021. Notice of Investigation at 1, EDIS Doc. No. 749538 (Aug. 13, 2021); 86 Fed. Reg. 46275-76 (Aug. 18, 2021). The complaint, as amended, alleges violations of section 337 of the Tariff Act of 1930, as amended, by reason of infringement of certain claims of U.S. Patent No. 10,912,501 ("the '501 patent"), U.S. Patent No. 10,912,502 ("the '502 patent"), U.S. Patent 10,945,648 ("the '648 patent"), U.S. Patent No. 10,687,745 ("the '745 patent"), and U.S. Patent No. 7,761,127 ("the '127 patent"). *Id*. The Commission ordered institution of this investigation to determine "whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products . . . by reason of infringement of one or more of claims 1-9 and 11-30 of the '501 patent; claims 1-2, 4-6, 8-12, 14-22, 24-26, and 28-30 of the '502 patent; claims 1-17 and 19-30 of the '648 patent; claims 1-6, 8-9, 11, 14, 20-24, and 26-27 of the '745 patent; and claims 7-9 of the '127 patent; and whether an industry in the United States exists as required by subsection (a)(2) of section 337." *Id.* at 2. The investigation was instituted upon publication of the Notice of Investigation in the Federal Register on Monday, August 18, 2021. 86 Fed. Reg. 46275-76.

Respondent Apple Inc. filed a response to the Amended Complaint and Notice of Investigation on September 7, 2021 (the "Response to Complaint"), disputing Complainants'

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allegations with respect to infringement and domestic industry and asserting affirmative defenses of invalidity and unenforceability. *See* EDIS Doc. ID 752521.¹

Pursuant to Order No. 3 (Sept. 1, 2021), the target date of this investigation was set to be December 16, 2022. On September 13, 2021, the investigation was assigned by then Chief Administrative Law Judge Bullock to the undersigned. *See* Notice to the Parties, EDIS Doc. ID 751531 (Sept. 13, 2021). Pursuant to Order No. 5 (Sept. 22, 2021), the target date was extended to January 16, 2023. *See* Comm'n Notice (Oct. 12, 2021), EDIS Doc. ID 754020.

A technology tutorial and *Markman* hearing was held on February 17, 2022. *See Markman* Tr., EDIS Doc. ID 763489.²

Pursuant to Order No. 25 (Mar. 23, 2022), Complainants withdrew their allegations of infringement with respect to claims 2, 4, 5, 7, 11, 16, 19, 20, and 22-30 of the '501 patent, claims 1-2, 4-6, 8-12, 14-18, 20, 25, and 26 of the '502 patent, claims 3, 4, 6, 7, 9, 10, 13-17, 19, 22, and 25-28 of the '648, and claims 1, 3-6, 8, 11, 14, 20-24, and 26 of the '745 patent. *See* Comm'n Notice, EDIS Doc. ID 768023 (Apr. 12, 2022). Pursuant to Order No. 33 (May 20, 2022), Complainants withdrew their allegations of infringement with respect to claims 1, 3, 6, 8, 9, 13-15, 17, 18, and 21 of the '501 patent, claims 19, 21, 24, 29, and 30 of the '502 patent, claims 1, 2, 5, 8, 11, 20, 21, 23, and 29 of the '648, and claim 2 of the '745 patent. *See* Comm'n Notice, EDIS Doc. ID 772826 (Jun. 10, 2022).

¹ The affirmative defenses based on inequitable conduct were stricken pursuant to Order No. 9 (Dec. 20, 2021), and Respondent was subsequently granted leave to add certain inequitable conduct defenses pursuant to Order No. 23 (Mar. 23, 2022).

² All of the claim construction disputes raised at the *Markman* hearing were subsequently mooted by the withdrawal of asserted claims or by agreement of the parties. *See infra*.

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An evidentiary hearing was held on June 6-10, 2022. The parties filed initial post-hearing briefs on June 27, 2022, and filed post-hearing reply briefs on July 11, 2022. Additional exhibits were admitted pursuant to Order No. 50 (Jun. 16, 2022) and Order No. 56 (Aug. 31, 2022). The hearing transcript was amended pursuant to Order No. 51 (Jun. 23, 2022) and Order No. 52 (Jun. 27, 2022). The parties' post-hearing briefs were amended pursuant to Order No. 54 (Jul. 14, 2022), Order No. 55 (Jul. 14, 2022), and Order No. 57 (Aug. 31, 2022).

Pursuant to Order No. 58 (Sept. 12, 2022), Order No. 59 (Oct. 24, 2022), and Order No. 61 (Dec. 9, 2022), the target date was extended to May 10, 2023. *See* Comm'n Notice, EDIS Doc. ID 787448 (Jan. 6, 2023).

B. The Parties

1. Complainants

The Complainants are Masimo Corporation ("Masimo") and Cercacor Laboratories, Inc. ("Cercacor") (collectively, "Complainants"). Notice of Investigation at 2. Masimo and Cercacor are both Delaware corporations having their principal places of business in Irvine, California. Complaint ¶ 9. Masimo is the owner of the '501 patent (JX-0001), '502 patent (JX-0002), '648 patent (JX-0003), and '745 patent (JX-0009). *Id.* ¶ 4. Cercacor is the owner of the '127 patent (JX-0007). *Id.* Masimo and Cercacor have rights to each of the asserted patents through a cross-licensing agreement. *Id.* ¶¶ 4, 77; CX-1612C.

2. Respondent

The Respondent is Apple Inc. ("Apple"). Notice of Investigation at 2. Apple is a California corporation having its principal place of business in Cupertino, California. Response to Complaint ¶ 21.

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C. Asserted Patents

The '501 patent, '502 patent, and '648 patent share a common specification, claiming priority to an application filed on July 3, 2008. JX-0001; JX-0002; JX-0003. These patents are entitled "User-Worn Device for Noninvasively Measuring a Physiological Parameter of a User," naming inventors Jeroen Poeze *et al.*, and are referenced herein as the "Poeze patents." *Id.*

The '745 patent is entitled "Physiological Monitoring Devices, Systems, and Methods," and claims priority to an application filed on June 28, 2016, naming inventor Ammar Al-Ali. JX-0009.

The '127 patent is entitled "Multiple Wavelength Sensor Substrate" and issued from an application filed on March 1, 2006, naming inventors Ammar Al-Ali *et al.* JX-0007.

D. Products at Issue

The products at issue are "wearable electronic devices with light-based pulse oximetry functionality and components thereof." Notice of Investigation at 2.

1. Accused Products

Complainants accuse Apple Watch products of infringing the asserted patents, including the Apple Watch Series 6, the Apple Watch Series 7, and certain prototype Apple Watch products

("Next Generation Apple Watches"). CIB at 37-39. Apple has stipulated to the importation of the Apple Watch Series 6, Apple Watch Series 7, and Next Generation Apple Watches (collectively, the "Accused Products"). See CX-0128C (Stipulation Regarding Importation and Inventory) at ¶¶ 2-4; CX-1259C (Stipulation Relating to Next-Generation Watches) at ¶¶ 5-6. The parties have stipulated that the Accused Products are materially identical for the purposes of infringement in this investigation. See Joint Stipulation of Facts at ¶¶ 11-13, EDIS Doc. ID 770692 (May 13, 2022); CX-1259C at ¶¶ 7-8.

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2. Domestic Industry Products

With respect to the '501, '502, '648, and '745 patents, Complainants rely on certain "Masimo Watch" products. CIB at 26-35. These Masimo Watch products include certain prototypes identified as the "Circle Sensor" (CPX-0021C), the "Wings Sensor" (CPX-0029C), the "RevA sensor" (CPX-0052C), the "RevD sensor" (CPX-0058C), the "RevE sensors" (CPX-0019C, CPX-0020C, CPX-0065C), and a product identified as the Masimo W1 Watch (CPX-0146C). CIB at 30-35. With respect to the '127 patent, Complainants rely on certain of Masimo's rainbow® sensors. *Id.* at 36.

E. Witness Testimony

The undersigned received testimonial evidence in this investigation in the form of live testimony and deposition designations.

1. Fact Witnesses

The first witness at the hearing was Joe Kiani, the chairman and chief executive officer of Masimo and Cercacor. Tr. at 79-189. Complainants also presented testimony from Mohamed Diab, an engineer at Masimo, *id.* at 190-246; Ammar Al-Ali, who oversees technology development at Masimo, *id.* at 247-340; and Bilal Muhsin, who is the chief operating officer of Masimo. *Id.* at 341-89. Complainants further presented testimony from Stephen Scruggs, the director of sensor design at Masimo, *id.* at 390-479; Micah Young, who is Masimo's chief financial officer and executive vice president, *id.* at 481-520; and Jeroen Hammarth, the chief financial officer of Cercacor. *Id.* at 521-33.

Apple presented testimony from several of its employees, including Vivek Venugopal, an optical engineer, *id.* at 816-49; Saahil Mehra, who manages product design for the Apple Watch health sensors, *id.* at 850-94; Ueyn Block, who worked on the optical architecture for the Apple

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Watch health sensors, *id.* at 895-917; Stephen Waydo, who is the director of a human interface device (HID) health group at Apple, *id.* at 918-51; Brian Land, who leads a health sensing hardware group at Apple, *id.* at 952-92; and Paul Mannheimer, a sensor architect and scientist at Apple, *id.* at 993-1025. Apple's counsel also examined Scott Cromar, the prosecuting attorney for the '501 patent, '502 patent, and '648 patent. *Id.* at 1026-41. Apple further presented testimony from Robert Rowe, who was the named inventor of certain asserted prior art. *Id.* at 1141-53; *see id.* at 1174:3-1175:7 (no cross-examination for Mr. Rowe).

2. Expert Witnesses

Complainants rely on the testimony of Daniel McGavock, who was admitted as an expert in financial matters, offering testimony regarding economic domestic industry, bond, and commercial success. Tr. at 533-76 (expert qualification at 534:25-535:6), 1416-42. With respect to the '127 patent, Complainants rely on the testimony of Jack Goldberg, who was admitted as an expert in the field of physiological monitoring technologies. *Id.* at 612-63 (expert qualification at 614:3-11), 1391-1408. With respect to the '501 patent, '502 patent, '648 patent, and '745 patent, Complainants rely on the testimony of Vijay Madisetti, who was admitted as an expert in the field of physiological monitoring technologies. *Id.* at 664-813 (*voir dire* and expert qualification at 666:10-674:12). Complainants also rely on the testimony of Robert Stoll, who was admitted as an expert on Patent Office practice and procedure. *Id.* at 1409-15 (expert qualification at 1409:23-1410:4).

Apple relies on the testimony of Majid Sarrafzadeh, who was admitted as an expert in physiological monitoring technologies including the design of pulse oximetry sensors, with respect to the '745 patent and '127 patent. *Id.* at 1042-1138 (expert qualification at 1046:5-12). With respect to the '501 patent, '502 patent, and '648 patent, Apple relies on the testimony of

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Steven Warren, who was admitted as an expert in biomedical engineering, medical monitoring systems, biomedical instrumentation, biomedical optics, light issue interaction, diagnostic systems, wearable sensors, and biomedical signal processing. *Id.* at 1181-1282 (expert qualification at 1187:20-1188:11). Apple also relies on the testimony of Vincent Thomas, who was admitted as an expert in the field of economics and financial analysis, with respect to the economic prong of the domestic industry requirement. *Id.* at 1282-1389 (expert qualification at 1283:11-17).

3. Deposition Designations

Complainants submitted several designated deposition transcripts that were received into evidence without a sponsoring witness: CX-0273C (Amor Dep. Tr.); CX-0281C (Block Dep. Tr.); CX-0275C (Caldbeck Dep. Tr.); CX-0283C (Charbonneau-Lefort Dep. Tr.); CX-0285C (Dua Dep. Tr.); CX-0287C (Land Dep. Tr.); CX-0289C (Mannheimer Dep. Tr.); CX-0291C (Mehra Dep. Tr.); CX-0293C (Rollins Dep. Tr.); CX-0279C (Rowe Dep. Tr.); CX-0295C (Shui Dep. Tr.); CX-0297C (Venugopal Dep. Tr.); CX-0299C (Waydo Dep. Tr.). *See* Tr. at 291:22-299:5. Apple also submitted several designated deposition transcripts that were received into evidence without a sponsoring witness: RX-1195C (Abdul-Hafiz Dep. Tr.); RX-1296C (Al-Ali Dep. Tr.); RX-1200C (Diab Dep. Tr.); RX-1201C (Hammarth Dep. Tr.); RX-1202C (Kaufman Dep. Tr.); RX-1204C (Kiani Dep. Tr.); RX-1206C (Muhsin Dep. Tr.); RX-1209C (Scruggs Dep. Tr.); RX-1210C (Scruggs 2nd Dep. Tr.); RX-1211C (Young Dep. Tr.). *See* Tr. at 1323:24-1324:20.

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II. JURISDICTION AND IMPORTATION

A. Personal Jurisdiction

Apple has submitted to the personal jurisdiction of the Commission by answering the Complaint and Notice of Investigation, participating in discovery, appearing at hearings, and filing motions and briefs. *See Certain Miniature Hacksaws*, Inv. No. 337-TA-237, USITC Pub. No. 1948, Initial Determination at 4, 1986 WL 379287, *1 (Oct. 15, 1986), *not reviewed in relevant part by* Comm'n Action and Order, 1987 WL 450871 (Jan. 15, 1987). Apple does not dispute the Commission's jurisdiction in this investigation. *See* RIB at 18.

B. In Rem Jurisdiction and Importation

The Commission has *in rem* jurisdiction over the accused products by virtue of their importation into the United States. *See Sealed Air Corp. v. U.S. Int'l Trade Comm'n*, 645 F.2d 976, 985-86 (C.C.P.A. 1981) (holding that the ITC's jurisdiction over imported articles is sufficient to exclude such articles). Apple has stipulated to the importation of the Accused Products. CX-0128C at 1-2; CX-1259C ¶¶ 5-6. Apple does not dispute the Commission's jurisdiction in this investigation. *See* RIB at 18.

III. LEGAL STANDARDS

A. Infringement

Section 337(a)(1)(B)(i) prohibits "the importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that – (i) infringe a valid and enforceable United States patent or a valid and enforceable United States copyright registered under title 17." 19 U.S.C. §1337(a)(1)(B)(i). The Commission has held that the word "infringe" in Section 337(a)(1)(B)(i) "derives its legal meaning from 35 U.S.C. § 271, the section of the Patent Act that defines patent infringement."

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Certain Elec. Devices with Image Processing Sys., Components Thereof, and Associated Software, Inv. No. 337-TA-724, Comm'n Op. at 13-14, EDIS Doc. ID 467105 (Dec. 21, 2011).

Infringement must be proven by a preponderance of the evidence. *SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988). The preponderance of the evidence standard "requires proving that infringement was more likely than not to have occurred." *Warner-Lambert Co. v. Teva Pharm. USA, Inc.*, 418 F.3d 1326, 1341 n.15 (Fed. Cir. 2005).

1. Claim Construction

"An infringement analysis entails two steps. The first step is determining the meaning and scope of the patent claims asserted to be infringed. The second step is comparing the properly construed claims to the device accused of infringing." Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996) (citation omitted). "[T]he construction of claims is simply a way of elaborating the normally terse claim language[] in order to understand and explain, but not to change, the scope of the claims." Embrex, Inc. v. Serv. Eng'g Corp., 216 F.3d 1343, 1347 (Fed. Cir. 2000) (alterations in original) (quoting Scripps Clinic v. Genentech, Inc., 927 F.2d 1565, 1580 (Fed. Cir. 1991)). "[O]nly those [claim] terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy." Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc., 200 F.3d 795, 803 (Fed. Cir. 1999). The words of a claim "are generally given their ordinary and customary meaning," which is "the meaning that the term would have to a person of ordinary skill in art" as of the date that the patent application was filed. Phillips v. AWH Corp., 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc) (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)).

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2. Direct and Indirect Infringement

A patent claim is directly infringed when a respondent "makes, uses, offers to sell, or sells any patented invention, within the United States, or imports into the United States any patented invention" without consent of the patent owner. 35 U.S.C. § 271(a)

In addition to direct infringement, a respondent may be liable for indirect infringement, including induced infringement, which is defined in section 271(b) of the Patent Act: "Whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). See DSU Med. Corp. v. JMS Co., Ltd., 471 F.3d 1293, 1305 (Fed. Cir. 2006) (en banc) ("To establish liability under section 271(b), a patent holder must prove that once the defendants knew of the patent, they actively and knowingly aided and abetted another's direct infringement.") (citations omitted). "The mere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven." *Id.* (citations omitted). The Supreme Court has held that induced infringement "requires knowledge that the induced acts constitute patent infringement." Global-Tech Appliances, Inc. v. SEB S.A., 563 U.S. 754, 766 (2011). In Suprema, Inc. v. Int'l Trade Comm'n, the Federal Circuit upheld the Commission's interpretation of the section 337 language "articles that infringe" in the context of induced infringement, holding that the statute "covers goods that were used by an importer to directly infringe post-importation as a result of the seller's inducement." 796 F.3d 1338, 1352-53 (Fed. Cir. 2015).

Another form of indirect infringement is contributory infringement, defined in section 271(c) of the Patent Act: "Whoever offers to sell . . . or imports into the United States a component of a patented machine, . . . or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or

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especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer." 35 U.S.C. § 271(c). The intent requirement for contributory infringement requires that respondent knows "that the combination for which [the] component was especially designed was both patented and infringing." *Global-Tech*, 563 U.S. at 763. A violation of section 337 based on contributory infringement requires that "the accused infringer imported, sold for importation, or sold after importation within the United States, the accused components that contributed to another's direct infringement." *Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1353 (Fed. Cir. 2010).

3. Literal Infringement and the Doctrine of Equivalents

A complainant must prove either literal infringement or infringement under the doctrine of equivalents. Literal infringement requires the patentee to prove that the accused device meets each and every limitation of the asserted claim(s). Frank's Casing Crew & Rental Tools, Inc. v. Weatherford Int'l, Inc., 389 F.3d 1370, 1378 (Fed. Cir. 2004). "If even one limitation is missing or not met as claimed, there is no literal infringement." Elkay Mfg. Co. v. EBCO Mfg. Co., 192 F.3d 973, 980 (Fed. Cir. 1999). Literal infringement is a question of fact. Finisar Corp. v. DirecTV Grp., Inc., 523 F.3d 1323, 1332 (Fed. Cir. 2008). Under the doctrine of equivalents, "a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 21 (1997).

B. Invalidity

It is the respondents' burden to prove invalidity, and the burden of proof never shifts to

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the patentee to prove validity. *Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V.*, 528 F.3d 1365, 1380 (Fed. Cir. 2008). "Under the patent statutes, a patent enjoys a presumption of validity, *see* 35 U.S.C. § 282, which can be overcome only through facts supported by clear and convincing evidence" *SRAM Corp. v. AD-II Eng'g, Inc.*, 465 F.3d 1351, 1357 (Fed. Cir. 2006); *see also Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 100-114 (2011) (upholding the "clear and convincing" standard for invalidity).

The clear and convincing evidence standard placed on the party asserting an invalidity defense requires a level of proof beyond the preponderance of the evidence. Although not susceptible to precise definition, "clear and convincing" evidence has been described as evidence that produces in the mind of the trier of fact "an abiding conviction that the truth of a factual contention is 'highly probable." *Price v. Symsek*, 988 F.2d 1187, 1191 (Fed. Cir. 1993) (quoting *Buildex, Inc. v. Kason Indus., Inc.*, 849 F.2d 1461, 1463 (Fed. Cir. 1988)).

1. Anticipation

Pursuant to 35 U.S.C. § 102, a patent claim is invalid as anticipated if:

- (1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or
- (2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

35 U.S.C. § 102 (2012). "A patent is invalid for anticipation if a single prior art reference discloses each and every limitation of the claimed invention. Moreover, a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily

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present, or inherent, in the single anticipating reference." *Schering Corp. v. Geneva Pharm., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003) (citations omitted).

2. Obviousness

Section 103 of the Patent Act states:

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

35 U.S.C. § 103(a) (2012).

"Obviousness is a question of law based on underlying questions of fact." *Scanner Techs.*, 528 F.3d at 1379. The underlying factual determinations include: "(1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art, and (4) objective indicia of non-obviousness." *Id.* at 1380 (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966)). These factual determinations are often referred to as the "*Graham* factors."

A critical inquiry in determining the differences between the claimed invention and the prior art is whether there is a reason to combine the prior art references. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418-21 (2007). In *KSR*, the Supreme Court rejected the Federal Circuit's rigid application of a "teaching-suggestion-motivation" test—while the Court stated that "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does," it described a more flexible analysis:

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Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue As our precedents make clear, however, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.

Id. at 418. Applying *KSR*, the Federal Circuit has held that, where a patent challenger contends that a patent is invalid for obviousness based on a combination of prior art references, "the burden falls on the patent challenger to show by clear and convincing evidence that a person of ordinary skill in the art would have had reason to attempt to make the composition or device . . . and would have had a reasonable expectation of success in doing so." *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007).

In addition to demonstrating that a reason exists to combine prior art references, the challenger must demonstrate that the combination of prior art references discloses all of the limitations of the claims. *Hearing Components, Inc. v. Shure Inc.*, 600 F.3d 1357, 1373-1374 (Fed. Cir. 2010), *abrogated on other grounds by Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898 (2014) (upholding finding of non-obviousness based on substantial evidence that the asserted combination of references failed to disclose a claim limitation); *Velander v. Garner*, 348 F.3d 1359, 1363 (Fed. Cir. 2003) (explaining that a requirement for a finding of obviousness is that "all the elements of an invention are found in a combination of prior art references").

3. Indefiniteness

"The Patent Act requires that a patent specification 'conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as [the] invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898 (2014)

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(quoting 35 U.S.C. § 112, ¶ 2). "[T]he second paragraph of § 112 contains two requirements: first, [the claim] must set forth what the applicant regards as his invention, and second, it must do so with sufficient particularity and distinctness, *i.e.*, the claim must be sufficiently definite." *Allen Eng'g Corp. v. Bartell Indus., Inc.,* 299 F.3d 1336, 1348 (Fed. Cir. 2002) (citation and internal quotation marks omitted) (alteration in original). A claim does not satisfy the second requirement and is thereby indefinite "if read in light of the specification delineating the patent, and the prosecution history, [the claim] fail[s] to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus*, 534 U.S. at 901. Indefiniteness is a question of law, subject to a determination of underlying facts. *Akzo Nobel Coatings, Inc. v. Dow Chem. Co.*, 811 F.3d 1334, 1343-44 (Fed. Cir. 2016). The party challenging the validity of a claim bears the burden of establishing indefiniteness. *Id*.

4. Written Description

Under 35 U.S.C. § 112, ¶ 1, the specification must provide a written description of the claimed invention that "reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharm., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*). Determining whether the written description requirement has been satisfied "requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art" to determine whether the specification "show[s] that the inventor actually invented the invention claimed." *Id.*

5. Enablement

The enablement requirement is set forth in 35 U.S.C. § 112, ¶ 1 and provides in pertinent part that the specification shall describe "the manner and process of making and using [the

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invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the [invention]." The "enablement requirement is satisfied when one skilled in the art, after reading the specification, could practice the claimed invention without undue experimentation." *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1244 (Fed. Cir. 2003). Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

C. Inequitable Conduct

A patent containing a claim obtained through inequitable conduct is unenforceable. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1288-89 (Fed. Cir. 2011) (en banc). "Moreover, the taint of a finding of inequitable conduct can spread from a single patent to render unenforceable other related patents and applications in the same technology family." *Id.* (*citing Consol. Aluminum Corp. v. Foseco Int'l Ltd.*, 910 F.2d 804, 808-12 (Fed. Cir. 1990)).

"To prevail on the defense of inequitable conduct, the accused infringer must prove that the applicant misrepresented or omitted material information with the specific intent to deceive the PTO." *Id.* at 1287. The failure to disclose a reference to the PTO constitutes inequitable conduct only if "the applicant *made a deliberate decision* to withhold a known material reference." *Id.* at 1290 (quoting *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1182 (Fed. Cir. 1995)) (internal quotation marks omitted; emphasis in original). "In other words, the accused infringer must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it." *Id.* Inequitable conduct based on the failure to disclose a reference requires a showing of "but for" materiality for the reference. *Id.* at 1291. The "but for" materiality requirement is satisfied "if the PTO"

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would not have allowed a claim had it been aware of the undisclosed prior art." *Id.* In determining whether "but for" materiality requirement is satisfied, the "the court should apply the preponderance of the evidence standard and give claims their broadest reasonable construction." *Id.* at 1291-92.

While deceptive intent may be inferred solely from circumstantial evidence, "[t]o meet the clear and convincing evidence standard, the specific intent to deceive must be 'the single most reasonable inference able to be drawn from the evidence." *Id.* (quoting *Star Scientific Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008)).

D. Domestic Industry

In patent-based proceedings under section 337, a complainant must establish that an industry "relating to the articles protected by the patent . . . exists or is in the process of being established" in the United States. 19 U.S.C. § 1337(a)(2). Under Commission precedent, the domestic industry requirement of section 337 consists of a "technical prong" and an "economic prong." *See, e.g., Alloc, Inc. v. Intl Trade Comm'n,* 342 F.3d 1361, 1375 (Fed. Cir. 2003).

To meet the technical prong, the complainant must establish that it practices at least one claim of the asserted patent. *Certain Point of Sale Terminals and Components Thereof*, Inv. No. 337-TA-524, Order No. 40 at 17-18, EDIS Doc. ID 230409 (Apr. 11, 2005). "The test for satisfying the 'technical prong' of the industry requirement is essentially [the] same as that for infringement, *i.e.*, a comparison of domestic products to the asserted claims." *Alloc*, 342 F.3d at 1375.

With respect to the "economic prong," subsection (3) of Section 337(a) provides:

For purposes of paragraph (2), an industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent, copyright, trademark, mask work, or design concerned –

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- (A) significant investment in plant and equipment;
- (B) significant employment of labor or capital; or
- (C) substantial investment in its exploitation, including engineering, research and development, or licensing.

19 U.S.C. § 1337(a)(3).

Expenditures may be counted toward satisfaction of the domestic industry requirement "as long as those investments pertain to the complainant's industry with respect to the articles protected by the asserted IP rights." Certain Television Sets, Television Receivers, Television Tuners, and Components Thereof, Inv. No. 337-TA-910, Comm'n Op. at 68, 2015 WL 6755093, at *36 (Oct. 30, 2015); accord, e.g., Certain Marine Sonar Imaging Devices, Including Downscan and Sidescan Devices, Prods. Containing the Same, and Components Thereof, Inv. No. 337-TA-921, Comm'n Op., 2016 WL 10987364, at *40 (Jan. 6, 2016) ("Navico's allocation methodology reasonably approximates the warranty and technical customer support expenditures relating to the LSS-1 product.") (citing Certain Ground Fault Circuit Interrupters and Prods. Containing Same, Inv. No. 337-TA-739, Comm'n Op. at 74-75, 79-81 (June 8, 2012)). Subsections (A), (B), and (C) are listed in the disjunctive, and accordingly, the domestic industry investments in plant and equipment or labor and capital can include expenditures that relate to engineering or research and development. Certain Solid State Storage Drives, Stacked Electronics Components, and Products Containing Same, Inv. No. 337-TA-1097, Comm'n Op. at 14, EDIS Doc. ID 649139 (June 29, 2018) ("[T]he text of the statute, the legislative history, and Commission precedent do not support narrowing subsections (A) and (B) to exclude nonmanufacturing activities, such as investments in engineering and research and development.").

Whether a complainant satisfies the economic prong is not analyzed according to a rigid mathematical formula. *Certain Male Prophylactic Devices*, Inv. No. 337-TA-546, Comm'n Op.

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at 39, EDIS Doc. ID 279161 (Aug. 1, 2007). The decision is made on a case-by-case basis and requires "an examination of the facts in each investigation, the article of commerce, and the realities of the marketplace." *Id.* Although Section 337(a)(3) describes the economic activities as "significant" and "substantial," a complainant does not need to show any "minimum monetary expenditure," and a complainant does not "need to define or quantify the industry itself in absolute mathematical terms." *Stringed Musical Instruments & Components Thereof* ("*Stringed Musical Instruments*"), Inv. No. 337-TA-586, Comm'n Op. at 26, EDIS Doc. ID 300615 (May 16, 2008). "A precise accounting [of the complainant's domestic investments] is not necessary, as most people do not document their daily affairs in contemplation of possible litigation." *Id.* at 17.

The Commission has held that "[o]rdinarily, the relevant date at which to determine if the domestic industry requirement of section 337 is satisfied is the filing date of the complaint." *Certain Thermoplastic-Encapsulated Electric Motors, Components Thereof, and Products and Vehicles Containing the Same*, Inv. No. 337-TA-1073, Comm'n Op. at 6-7, EDIS Doc. ID 684974 (Aug. 12, 2019). In *Stringed Musical Instruments*, the Commission held that a domestic industry is in the process of being established when (1) a complainant takes "the necessary tangible steps to establish such an industry in the United States," and (2) there is a "significant likelihood that the industry requirement will be satisfied in the future." Inv. No. 337-TA-586, Comm'n Op. at 14-17, EDIS Doc. ID 300615 (May 16, 2008).

IV. POEZE PATENTS

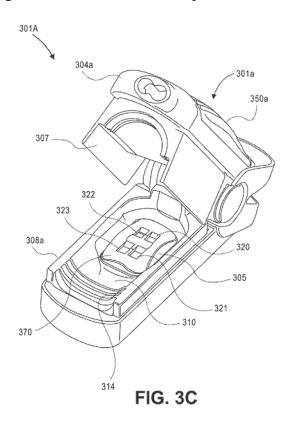
The '501 patent, '502 patent, and '648 patent are entitled "User-Worn Device for Noninvasively Measuring a Physiological Parameter of a User," sharing a common specification and naming inventors Jeroen Poeze *et al.* JX-0001; JX-0002; JX-0003. These patents are

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collectively referred to herein as the "Poeze patents." The Poeze patents issued from applications filed on September 24, 2020, claiming priority to earlier patent applications, with the earliest provisional application filed on July 3, 2008. *See Id*.

A. Specification

The Poeze patents' specification describes non-invasive physiological sensors for measuring blood constituents or analytes using multi-stream spectroscopy. JX-0001 at 7:18-26. These sensors use an emitter that can uses optical radiation at different wavelengths to measure blood analytes like glucose, hemoglobin, or oxygen saturation. *Id.* at 12:13-13:58. The sensors are connected to handheld or portable monitoring devices that can be attached to a patient's body. *Id.* at 16:31-17:19. In one embodiment, the housing is designed to receive a patient's finger, which can be placed on a protrusion (305) that includes openings or windows (320, 321, 322, and 323) that allow light from the emitter to reach photodetectors. *Id.* at 19:13-20:15.



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Id. at Fig. 3C. One portion of the housing may include LEDs that emit optical radiation passing through a finger before being received by the photodetectors on the other portion of the housing. *Id.* at 26:30-27:41.

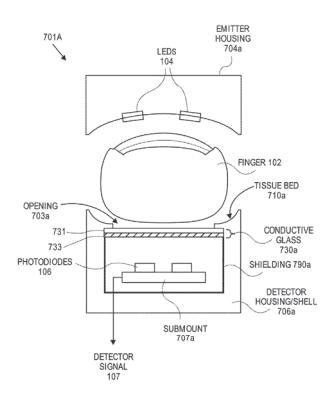


FIG. 7A

Id. at Fig. 7A.

B. Asserted claims

Masimo asserts claim 12 of the '501 patent, which depends from claim 1. *See* CIB at 53-66. Claims 1 and 12 of the '501 patent are recited below:

- 1. A user-worn device configured to non-invasively measure a physiological parameter of a user, the user-worn device comprising:
- at least three light emitting diodes (LEDs);
- at least three photodiodes arranged on an interior surface of the user-worn device and configured to receive light attenuated by tissue of the user;

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a protrusion arranged over the interior surface, the protrusion comprising a convex surface and a plurality of openings extending through the protrusion and positioned over the three photodiodes, the openings each comprising an opaque lateral surface, the plurality of openings configured to allow light to reach the photodiodes, the opaque lateral surface configured to avoid light piping through the protrusion; and

one or more processors configured to receive one or more signals from the photodiodes and calculate a measurement of the physiological parameter of the user.

JX-0001 at 45:2-19.

12. The user-worn device of claim 1, wherein the convex surface of the protrusion is an outermost surface configured to contact the tissue of the user and conform the tissue into a concave shape.

Id. at 46:4-8.

Masimo also asserts claim 22 of the '502 patent, which depends from claims 19, 20, and 21, and claim 28, a separate independent claim. *See* CIB at 66-77. These claims of the '502 patent are recited below:

- 19. A user-worn device configured to non-invasively measure an oxygen saturation of a user, the user-worn device comprising:
- a plurality of emitters configured to emit light, each of the emitters comprising at least two light emitting diodes (LEDs);
- four photodiodes arranged within the user-worn device and configured to receive light after at least a portion of the light has been attenuated by tissue of the user;
- a protrusion comprising a convex surface including separate openings extending through the protrusion and lined with opaque material, each opening positioned over a different one associated with each of the four photodiodes, the opaque material configured to reduce an amount of light reaching the photodiodes without being attenuated by the tissue;
- optically transparent material within each of the openings; and
- one or more processors configured to receive one or more signals from at least one of the four photodiodes and output measurements responsive to the one or more signals, the measurements indicative of the oxygen saturation of the user.
- 20. The user-worn device of claim 19 further comprising a thermistor.

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- 21. The user-worn device of claim 20, wherein the one or more processors are further configured to receive a temperature signal from the thermistor and adjust operation of the user-worn device responsive to the temperature signal.
- 22. The user-worn device of claim 21, wherein the plurality of emitters comprise at least four emitters, and wherein each of the plurality of emitters comprises a respective set of at least three LEDs.

JX-0002 at 46:22-54.

- 28. A user-worn device configured to non-invasively measure an oxygen saturation of a user, the user-worn device comprising:
- a first set of light emitting diodes (LEDs), the first set of LEDs comprising at least an LED configured to emit light at a first wavelength and an LED configured to emit light at a second wavelength;
- a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising at least an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength;
- four photodiodes arranged in a quadrant configuration on an interior surface of the user-worn device and configured to receive light after at least a portion of the light has been attenuated by tissue of the user;
- a thermistor configured to provide a temperature signal;
- a protrusion arranged above the interior surface, the protrusion comprising:
- a convex surface;
- a plurality of openings in the convex surface, extending through the protrusion, and aligned with the four photodiodes, each opening defined by an opaque surface configured to reduce light piping; and
- a plurality of transmissive windows, each of the transmissive windows extending across a different one of the openings;
- at least one opaque wall extending between the interior surface and the protrusion, wherein at least the interior surface, the opaque wall and the protrusion form cavities, wherein the photodiodes are arranged on the interior surface within the cavities;
- one or more processors configured to receive one or more signals from at least one of the photodiodes and calculate an oxygen saturation measurement of the user, the one or more processors further configured to receive the temperature signal;

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- a network interface configured to wirelessly communicate the oxygen saturation measurement to at least one of a mobile phone or an electronic network;
- a user interface comprising a touch-screen display, wherein the user interface is configured to display indicia responsive to the oxygen saturation measurement of the user;
- a storage device configured to at least temporarily store at least the measurement; and
- a strap configured to position the user-worn device on the user.

Id. at 47:13-23.

Masimo further asserts claim 12 of the '648 patent, which depends from claim 8, and claims 24 and 30, which depend from claim 20. *See* CIB at 77-83. These claims of the '648 patent are recited below:

- 8. A user-worn device configured to non-invasively determine measurements of a physiological parameter of a user, the user-worn device comprising:
- a first set of light emitting diodes (LEDs), the first set comprising at least an LED configured to emit light at a first wavelength and at least an LED configured to emit light at a second wavelength;
- a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength;

four photodiodes;

- a protrusion comprising a convex surface, at least a portion of the protrusion comprising an opaque material;
- a plurality of openings provided through the protrusion and the convex surface, the openings aligned with the photodiodes;
- a separate optically transparent window extending across each of the openings;
- one or more processors configured to receive one or more signals from at least one of the photodiodes and output measurements of a physiological parameter of a user;
- a housing; and

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a strap configured to position the housing proximate tissue of the user when the device is worn.

JX-0003 at 45:45-46:3.

12. The user-worn device of claim 8, wherein the physiological parameter comprises oxygen or oxygen saturation.

Id. at 46:15-16.

- 20. A user-worn device configured to non-invasively determine measurements of a user's tissue, the user-worn device comprising:
- a plurality of light emitting diodes (LEDs);
- at least four photodiodes configured to receive light emitted by the LEDs, the four photodiodes being arranged to capture light at different quadrants of tissue of a user;
- a protrusion comprising a convex surface and a plurality of through holes, each through hole including a window and arranged over a different one of the at least four photodiodes; and
- one or more processors configured to receive one or more signals from at least one of the photodiodes and determine measurements of oxygen saturation of the user.

Id. at 46:34-49.

24. The user-worn device of claim 20, wherein the protrusion comprises opaque material configured to substantially prevent light piping.

Id. at 46:59-61.

30. The user-worn device of claim 20, wherein the protrusion further comprises one or more chamfered edges.

Id. at 47:6-7.

C. Level of Ordinary Skill in the Art

The parties have stipulated to a level of ordinary skill in the art for the Poeze patents:

[A] person with a working knowledge of physiological monitoring technologies. The person would have had a Bachelor of Science degree in an academic discipline emphasizing the design of electrical, computer, or software technologies, in combination with training or at least one to two

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years of related work experience with capture and processing of data or information, including but not limited to physiological monitoring technologies. Alternatively, the person could have also had a Master of Science degree in a relevant academic discipline with less than a year of related work experience in the same discipline.

Joint Stipulation of Facts ¶ 12, EDIS Doc. ID 770692 (May 13, 2022).

D. Claim Construction

The parties dispute the construction of the terms "over"/"above" and the terms "openings"/"through holes" in the claims of the Poeze patents. *See* CIB at 42-53; RIB at 26-39; CRB at 13-19; RRB at 23-34.

1. "over"/"above"

Several of the asserted claims of the Poeze patents contain limitations describing a protrusion that is "arranged over" or "arranged above" an interior surface. *See* '501 patent claim 1 ("a protrusion arranged over the interior surface"); '502 patent claim 28 ("a protrusion arranged above the interior surface"). Other limitations describe openings that are "positioned over" or "arranged over" photodiodes. *See* '501 patent claim 1 ("a plurality of openings extending through the protrusion and positioned over the three photodiodes"); '502 patent claim 19 ("each opening positioned over a different one associated with each of the four photodiodes"); '648 claim 20 ("each through hole including a window and arranged over a different one of the at least four photodiodes").

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³ The parties both argue that certain claim construction arguments were waived because they were not previously raised, *see* RIB at 37-38, CRB at 19 n.4, RRB at 31 n.17, 33 n.22, but these claim construction disputes were clearly addressed in the parties' pre-hearing briefs and pertain to the plain and ordinary meaning of the terms at issue. *See* CPBH at 39-43; RPHB at 8-15. Ground Rule 9.2 does not preclude parties from citing additional evidence that was admitted at the hearing to support arguments that are consistent with their pre-hearing briefs.

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Apple interprets the "over" and "above" limitations to require that the claimed features be arranged vertically when the claimed device is in use. RIB at 26-34. Complainants argue that these terms refer to "the configuration of features of the device relative to each other, not to the position of the device relative to the Earth." CIB at 43. Both parties purport to rely on the ordinary meaning of these terms, without proposing any explicit construction. CIB at 42-49; RRB at 21.

Apple relies on the preambles of the asserted claims describing "a user-worn device configured to non-invasively measure a physiological parameter" to argue that the orientation of the claimed features must be considered when a device is in use. RIB at 27-28. Complainants dispute this interpretation, arguing that "configured to" refers to the design of the product, not the orientation of components. CIB at 45. Complainants argue that the devices described in the specification do not have a fixed orientation and that the embodiments of the invention show "that the protrusion is arranged over the photodiodes and their interior surface by extending across that surface." Id. at 43. Complainants note that the patent specification describes a variety of measurement sites without reference to any specific orientation. CRB at 14 (citing JX-0001 at 8:21-23, 10:15-27, 10:62-11:3, 11:45-55). Complainants cite an example in one embodiment of a material described as "over" the glass layer when it is depicted as below the layer in Figure 7A. Id. at 45-46 (citing JX-0001 at 27:59-62, Fig. 7A). Dr. Madisetti testified that Complainants' interpretation is consistent with the ordinary meaning of "over," citing the example of a bandage over a wound, explaining that "the Band-Aid is always over the scratch [ir]respective of the orientation of my hand." Tr. at 701:22-18.

Complainants also cite extrinsic evidence in Apple patents and prior art using the terms "over" and "above" to describe the arrangement of features similar to those claimed in the Poeze

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patents. CIB at 46-49. *See*, *e.g.*, U.S. Patent No. 10,687,718 (CX-0118) at 32:17-23 ("For example, a back surface may comprise a first semi-circular protrusion that extends over the portions of the back surface."), 35:38-55 (FIG. 222A depicts . . . a protrusion 2202 disposed over an optical opening 2204."); U.S. Patent App. Pub. No. 2021/0093237 (CX-0103) at ¶ 0065 ("In some embodiments, windows 1220 over the emitters may be integral with the back cover 107 and windows 120 over the detectors may be inset within the back cover 107."); U.S. Patent App. Pub. No. 2017/03255744 (CX-1806) at ¶ 0044 ("For example, the back surface can include one or more cavities having a corresponding opening and a protrusion located over each of the openings."); U.S. Patent No. 4,224,948 (RX-0670) at 9:51-56 ("wherein said first and second light obstructing means comprise a pair of annular rings extending above the surface of the lower face of said case whereby said rings are in contact with the skin of the wearer").

Apple argues that Complainants' interpretation of the "over" and "above" limitations would render these terms meaningless. RRB at 23-24. Apple cites figures in the specification that consistently describe the claimed protrusion and openings located on top of the photodiodes. *Id.* at 24-26 (citing JX-0001 at 24:28-33, Figures 3C, 4C, 7B). Apple argues that the specification's use of the term "over" within the phrase "spread over" is irrelevant to the meaning of the claim phrases "positioned over" and "arranged over." RIB at 25-26. Apple further argues that in the Apple patents and patent applications using the term "over," the descriptions refer to devices that are depicted in a face-down position, not when they are configured to measure blood oxygen. *Id.* at 26-28. Apple argues that the "configured to" language in the claims requires that that the features have a specific orientation when the device is in use. *Id.* at 28-29.

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In consideration of the parties' arguments and the evidence of record, the undersigned agrees with Complainants that the claim limitations using the terms "over" and "above" do not require a vertical arrangement of features in the context of the Poeze patents. The terms "over" and "above" are commonly understood words with ordinary meanings that can be understood by a lay judge. See Phillips, 415 F.3d at 1314. The undersigned agrees with Apple that the word "over" may be used to describe a vertical arrangement, but "over" can also be used to describe an arrangement where one feature covers another, as recognized by Dr. Madisetti's example of a bandage over a wound. Tr. (Madisetti) at 701:22-18. This is a common usage of the term "over" in the field of wearable medical equipment, e.g., a mask over one's mouth, or in the field of optical sensors, e.g., a filter over a lens. This is consistent with how the term "over" is used in the asserted claims of the Poeze patents, describing "a protrusion arranged over the interior surface" and openings "positioned over" or "arranged over" photodiodes. In the context of this claim language, the term "over" refers to an arrangement where one feature covers another—not the relative arrangement of these features in a vertical direction.⁴ The ordinary meaning of the claim language does not restrict the orientation of these features, and whether the claimed photodiodes

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⁴ The term "above" is only used in asserted claim 28 of the '502 patent to refer to "a protrusion arranged above the interior surface." The undersigned agrees with Complainants that the patent specification does not require any specific orientation of the device and that the term "above" thus refers to a position relative to the device's features and not to its orientation relative to the Earth. *See* CIB at 43-49; CRB at 15-16. This is also consistent with the usage of the term in a prior art reference relied upon for invalidity purposes by Apple where the term "above" is used to refer to rings that extend beyond a surface, regardless of vertical orientation. *See* RX-0670 (Cramer) at claim 5 ("a pair of annular rings extending above the surface of the lower face of said case"). It is also consistent with the testimony of Apple's expert, Dr. Warren, that "[a] detector can't detect light without some sort of opening above it." Tr. (Warren) at 1193:5-6; *see also* RIB at 61 (same). Apple argues that "Cramer does not disclose restrictions on orientation" (RRB at 29) but this fact weighs against Apple's proposed construction: if the Cramer device can be in any orientation, the term "above" should have a meaning independent from orientation.

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are facing upward or downward in relation to the Earth does not affect a device's satisfaction of this limitation.⁵

Accordingly, the undersigned finds that the terms "over" and "above" have their plain and ordinary meaning and do not require a vertical arrangement of features in a particular orientation.

2. "openings"/"through holes"

Several of the asserted claims (or claims from which the asserted claims depend) contain limitations describing "openings" that extend "through the protrusion." *See* '501 patent claim 1 ("a plurality of openings extending through the protrusion"); '502 patent claim 19 ("separate openings extending through the protrusion"), claim 28 ("a plurality of openings in the convex surface, extending through the protrusion"); '648 patent claim 8 ("a plurality of openings provided through the protrusion and the convex surface"). Claim 20 of the '648 patent describes "a plurality of through holes, each through hole including a window."

Apple argues that the claimed "openings" or "through holes" must not contain any material, such as glass or plastic. RIB at 34-39; RRB at 30-34; *id.* at 30 n.16 ("openings—like holes—require an absence of material"). Complainants submit that the claimed "openings" or "through holes" can contain a window of transparent material. CIB at 49-53; CRB at 17-18. Both parties purport to rely on the ordinary meaning of these terms, without proposing any explicit construction. CIB at 53; RRB at 30-31.

Complainants cite evidence in the claims and specification of the Poeze patents that the claimed "openings" and "through holes" can contain a window of transparent material. CIB at

⁵ Apple's arguments regarding the "configured to" language of the claim preambles are thus irrelevant to the construction of this limitation.

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49-51. Complainants submit that the purpose of these openings is to allow light to pass through, citing claim 1 of the '501 patent, which describes "the plurality of openings configured to allow light to reach the photodiodes." JX-0001 at claim 1. Complainants cite examples in the claims and specification of the Poeze patents describing transparent windows in the relevant openings and through holes. CIB at 49-51. Complainants further identify Apple patents that refer to "openings" and "windows." *Id.* at 52-53. In reply, Apple cites testimony of its engineers describing

RRB at 33-34.

Apple argues that an opening or a hole is "an absence of material, into which something can be placed." *Id.* at 32.

In consideration of the parties' arguments and the evidence of record, the undersigned agrees with Complainants that the ordinary meaning of "openings" and "through holes" in the context of the Poeze patents does not preclude transparent material placed in the claimed "openings" or "through holes." An "opening" or "hole" can refer to an absence of material, but this is not necessarily a requirement. For example, a skylight would still be an "opening" in a roof after a glass window is installed, and a swimming hole is still a "hole" when it is filled with water. The undersigned agrees with Complainants that the ordinary meaning of the terms "opening" and "hole" can include openings and holes that include material.

The claims and specification of the Poeze patents use the terms "openings" and "holes" in a way that is consistent with this ordinary meaning by referring to "openings" and "through holes" that may contain transparent material. *See, e.g.,* '502 patent claim 19 ("optically transparent material within each of the openings"), claim 28 ("a plurality of transmissive windows, each of the transmissive windows extending across a different one of the openings"); '648 patent claim 8 ("a separate optically transparent window extending across each of the

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openings"), claim 20 ("each through hole including a window"). The specification explicitly provides that "[t]he openings can be made from glass to allow attenuated light from a measurement site, such as a finger, to pass through to one or more detectors." JX-0001 at 8:26-30; *see also* JX-0001 at 19:38-48 (describing "openings or windows," which "allow light to pass from the measurement site to the photodetectors"), 27:20-27 ("One or more components of conductive glass 730b can be provided in the openings 703."). Figure 7B depicts conductive glass provided in the identified opening:

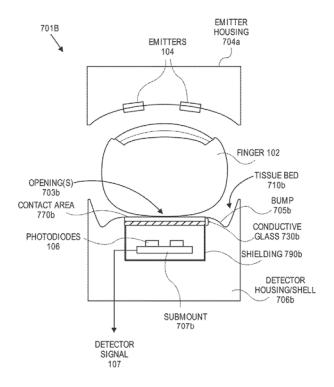


FIG. 7B

JX-0001 at Fig. 7B; *see id.* at 27:13-32. In view of these disclosures, the undersigned agrees with the testimony of Dr. Madisetti that the claimed "openings" and "through holes" in the Poeze patents can be made of glass or transparent material that allows light to pass through to the detectors. *See* Tr. (Madisetti) at 702:8-703:10.

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Apple argues that a "window" is something different from an "opening" or "hole," RIB at 37-38, but none of the statements in the specification cited by Apple suggest that an "opening" can no longer be referred to as an "opening" when filled with glass or covered by a window. To the contrary, the specification describes conductive glass that "can be provided in the openings." JX-0001 at 27:20-22. The claims of the Poeze patents repeatedly describe "windows extending across . . . the openings." '502 patent claim 28; see also '648 patent claim 8 (same); '648 patent, claim 20 ("each through hole including a window"). Claim 19 of the '502 patent describes "optically transparent material within each of the openings." The intrinsic evidence supports Complainants' interpretation of these terms to include "openings" and "through holes" that contain transparent material allowing for the transmission of light to the photodiodes.

Accordingly, the undersigned finds that the claimed "openings" and "through holes" can contain transparent material.

E. Infringement

Complainants allege that the Accused Products infringe claim 12 of the '501 patent, claims 22 and 28 of the '502 patent, and claims 12, 24, and 30 of the '648 patent. CIB at 53-83. There is no dispute with respect to the structure and operation of the Accused Products, and Apple only disputes infringement with respect to the "over"/"above" and "openings"/"through holes" limitations addressed above in the context of claim construction. RIB at 26-39; RRB at 20-34. Based on the evidence of record, and because Apple's proposed claim constructions have been rejected, the undersigned finds that these limitations are met, and that the Accused Products thus infringe each of the asserted claims, as discussed below.⁶

⁶ Apple's opening brief argues, in addition, that there is no indirect infringement of claim 28 of the '502 patent. See RIB at 39-40. Complainants do not provide any argument regarding indirect infringement.

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1. '501 Patent Claim 12⁷

a. Element [1 preamble]: "A user-worn device configured to noninvasively measure a physiological parameter of a user, the user-worn device comprising:"8

There is no dispute that the Accused Products meet the limitations of the preamble of claim 1, which requires "[a] user-worn device configured to non-invasively measure a physiological parameter of a user." *See* CIB at 59-60. Dr. Madisetti determined that the Accused Products are watches configured to measure blood oxygen saturation, relying on Apple's marketing materials and technical documentation. Tr. (Madisetti) at 679:12-680:5; CX-0281C (Block Dep. Tr.) at 71:21-72:5, 87:10-14, 177:10-178:7, 251:4-7; CX-1451 (Apple Watch advertisement) at 1:49; CX-1406 (Apple Watch User Guide); CX-1726 (Apple Watch Series 7 Technical Specifications). The evidence of record shows that this limitation is met.

b. Element [1A]: "at least three light emitting diodes (LEDs)"

There is no dispute that each of the Accused Products contains a sensor module with at least three LEDs. *See* CIB at 60-61. Dr. Madisetti identified four clusters of LEDs in each Accused Product, with each cluster containing three LEDs of different wavelengths. Tr. (Madisetti) at 680:6-22; CX-1548C (Apple Watch teardown photographs); CX-0281C (Block Dep. Tr.) at 65:5-67:20; CX-0026C (Apple Engineering Requirement Specification) at 7-8, 30-

Apple does not explain why an indirect infringement finding is needed to find a violation as to claim 28 of the '502 patent, or as to any other asserted claim (which are all apparatus claims).

⁷ Because claim 12 of the '501 patent depends from claim 1, the infringement, technical prong and invalidity analyses address the limitations of both claims 1 and 12. *See* CIB at xxvi.

⁸ The parties have stipulated that all preambles of all asserted claims are limiting. *See* Joint Stipulation of Facts ¶ 9, EDIS Doc. ID 770692 (May 13, 2022).

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32; CX-0059C (Apple Watch Series 7 Engineering Drawings) at 1-3. The evidence of record shows that this limitation is met.

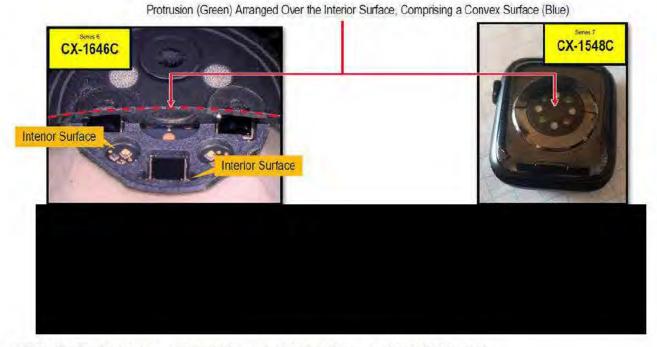
c. Element [1B]: "at least three photodiodes arranged on an interior surface of the user-worn device and configured to receive light attenuated by tissue of the user"

There is no dispute that each of the Accused Products contains at least three photodiodes on an interior surface that are configured receive light that has passed through the user's tissue. *See* CIB at 61-62. Dr. Madisetti identified four photodiodes arranged on Apple Watch sensor boards that are configured to receive light emitted from the LEDs after it has passed through the user's tissue. Tr. (Madisetti) at 680:23-681:11; CX-0281C (Block Dep. Tr.) at 70:13-16, 86:2-87:18; CX-0026C (Apple Engineering Requirement Specification) at 7-8, 30-32; CX-0059C (Apple Watch Series 7 Engineering Drawings) at 1-3. The evidence of record shows that this limitation is met.

d. Element [1C]: "a protrusion arranged over the interior surface, the protrusion comprising a convex surface"

Complainants identify a domed surface in the Accused Products as the claimed protrusion with a convex surface. CIB at 54-57. Dr. Madisetti identified this domed surface arranged over the interior surface of the Accused Products where the photodiodes are located. Tr. (Madisetti) at 681:12-682:11.

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CDX-0011C.016 (citing CX-1646C at 4; CX-1548C at 3; CX-0063C at 1).

Apple argues that the identified protrusion is not "over" the interior surface when the Accused Products are being used for blood oxygen monitoring (with the photodiodes pointed down toward the user's wrist). RIB at 26-34; RRB at 21-29. There is no dispute regarding the orientation of the Accused Products, but as discussed above in the context of claim construction, the claim term "over" does not require a particular vertical arrangement—the protrusion is "over" the interior surface because it is covering the interior surface.

Accordingly, the undersigned finds that the Accused Products meet the limitation requiring "a protrusion arranged over the interior surface."

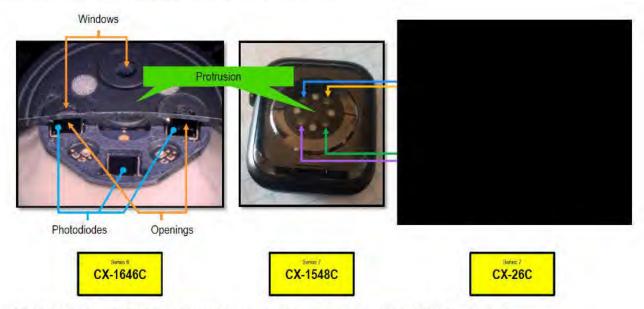
e. Element [1D]: "a plurality of openings extending through the protrusion and positioned over the three photodiodes"

Complainants identify openings in the Accused Products that are positioned over the four photodiodes. CIB at 57-59. Dr. Madisetti identified evidence

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that allow light to pass through to the photodiodes. Tr. (Madisetti) at 682:12-683:17.



CDX-0011C.017 (citing CX-1646C at 4; CX-1548C at 3; CX-0026C at 8, 31).

Apple argues that the alleged "openings" do not infringe this limitation because they are

RIB at 34-39; RRB at 29-34. Apple engineer Ueyn Block explained:

Tr. (Block) at 901:16-902:3. Apple also argues that the openings are not positioned "over" the photodiodes when the Accused Products are being used for blood oxygen

As discussed above in the context of claim construction, the undersigned finds that the claimed "openings" can contain transparent material. The fact that the openings in the Accused

monitoring (with the photodiodes pointed down toward the user's wrist). RIB at 26-39; RRB at

21-29.

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Products		does not
mean that these are no	ot "ope	enings" in accordance with the claim language. There is no dispute
that the	w	rithin the openings is transparent and allows for light to reach the
photodiodes. See CX	-0281	C (Block) at 272:2-9. There is also no dispute that each opening has
an opaque lateral surf	ace se	parating the opening from the surrounding material. See CIB at 62-
64; Part IV.E.1.f (Elec	nent 1	IE) infra.
The undersign	ed als	o finds that the openings are positioned "over" the four photodiodes.
As discussed above in	the c	ontext of claim construction, the claim term "over" does not require
particular vertical arra	ıngem	ent—the openings are positioned "over" the photodiodes because
they are aligned with	the ph	notodiodes and covering them.
Accordingly,	he Ac	cused Products meet the plurality of openings" limitation of '501
patent claim 1.		
	f.	Element [1E]: "the openings each comprising an opaque lateral surface, the plurality of openings configured to allow light to reach the photodiodes, the opaque lateral surface configured to avoid light piping through the protrusion"
There is no dis	spute t	that the Accused Products have opaque lateral surfaces in their
alleged openings that	are co	onfigured to avoid light piping. See CIB at 62-64. Apple engineers
described a		
		see also CV 0070C at 1; CV 0190C at 2; CV 1549C

at 3; CX-0072C at 26, 29-30. Dr. Madisetti considered this evidence to identify

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as opaque lateral surfaces meeting this limitation. Tr. (Madisetti) at 683:18-685:3. The evidence of record shows that this limitation is met.

g. Element 1[F]: "one or more processors configured to receive one or more signals from the photodiodes and calculate a measurement of the physiological parameter of the user"

There is no dispute that the Accused Products have processors that receive signals from the photodiodes and calculate measurements of physiological parameters. *See* CIB at 64-65. Dr. Madisetti identifies an application processor running Apple's algorithm to calculate oxygen saturation and pulse rate. Tr. (Madisetti) at 685:4-25; *see* CX-0013C (Apple Engineering Requirements Specification) at 12; CX-0100C (Apple Engineering Requirements Specification) at 6-31; CX-0072C at 3 (Apple Watch Series 6 BOM); CX-1726 (Apple Watch Series 7 Technical Specifications) at 2; CX-0299C (Waydo Dep. Tr.) at 38:10-40:6, 50:11-52:4. The evidence of record shows that this limitation is met.

h. Element [12]: "wherein the convex surface of the protrusion is an outermost surface configured to contact the tissue of the user and conform the tissue into a concave shape"

Claim 12 of the '501 patent depends from claim 1, further requiring that "the convex surface of the protrusion is an outermost surface configured to contact the tissue of the user and conform the tissue into a concave shape." There is no dispute that the Accused Products meet this limitation. See CIB at 65-66. As discussed above, Dr. Madisetti identified a convex protrusion in the Accused Products, and Apple documents and testimony confirm that the protrusion is designed

See

Tr. (Madisetti) at 686:1-18; CX-0281 (Block Dep. Tr.) at 200:6-14; CX-0063C (Apple Watch Series 7 Engineering Drawings) at 1; CX-1548C (photographs of Apple Watch Series 7) at 3;

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CX-0070C (Apple Watch Series 7 Engineering Drawings) at 1; CX-0010 (Apple website) at 3. The evidence of record shows that this limitation is met.

Accordingly, because each limitation of claims 1 and 12 are satisfied, the Accused Products infringe claim 12 of the '501 patent.

2. '502 Patent Claim 229

a. Element [19 preamble]: "A user-worn device configured to non-invasively measure an oxygen saturation of a user, the user worn device comprising:"

There is no dispute that the Accused Products meet the limitations of the preamble of '502 patent claim 19, which requires "[a] user-worn device configured to non-invasively measure an oxygen saturation of a user." *See* CIB at 67. The relevant evidence was discussed above in the context of the preamble of '501 patent claim 1. The evidence of record shows that this limitation is met.

b. Element [19A]: "a plurality of emitters configured to emit light, each of the emitters comprising at least two light emitting diodes (LEDs)"

There is no dispute that each of the Accused Products contains clusters of LEDs, with each cluster containing three LEDs. *See* CIB at 68. The relevant evidence was discussed above in the context of the "LEDs" limitation of '501 patent claim 1. The evidence of record shows that this limitation is met.

⁹ Because claim 22 of the '502 patent depends from claims 19, 20, and 21, the infringement, technical prong and invalidity analyses address the limitations of claims 19, 20, 21, and 22. *See* CIB at xxvii.

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c. Element [19B]: "four photodiodes arranged within the userworn device and configured to receive light after at least a portion of the light has been attenuated by tissue of the user"

There is no dispute that each of the Accused Products contains four photodiodes configured to receive light that has been attenuated by tissue of the user. *See* CIB at 68. The relevant evidence was discussed above in the context of the "photodiodes" limitation of '501 patent claim 1. The evidence of record shows that this limitation is met.

d. Element [19C]: "a protrusion comprising a convex surface including separate openings extending through the protrusion and lined with opaque material, each opening positioned over a different one associated with each of the four photodiodes, the opaque material configured to reduce an amount of light reaching the photodiodes without being attenuated by the tissue"

There is no dispute that each of the Accused Products contains a protrusion comprising a convex surface, as discussed above in the context of the "protrusion" limitation of '501 patent claim 1. See CIB at 66. With respect to the '502 patent claim 19 limitation requiring "openings extending through the protrusion," Complainants identify the same "openings" that are discussed above in the context of the "plurality of openings" limitation of '501 patent claim 1. See CIB at 66-67. Complainants further identify the same discussed above in the context of the "opaque lateral surfaces" limitation of '501 patent claim 1. Id.

Apple disputes infringement of this limitation based on its erroneous proposed constructions of the claim terms "over" and "openings." *See* RIB at 26-39; RRB at 21-34. These arguments have been rejected, however, as discussed above in the context of the "plurality of openings" limitation of '501 patent claim 1 and in the claim construction analysis above. *See* Part IV.D, *supra*. Accordingly, the undersigned finds that the Accused Products meet the limitation in '502 patent claim 19 requiring a "protrusion" including "openings extending

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through the protrusion" that are "lined with opaque material," and "each opening positioned over" the photodiodes.

e. Element [19D]: "optically transparent material within each of the openings"

There is no dispute that each of the Accused Products contains optically transparent material within each of the identified openings. *See* CIB at 68. The evidence for the presence of in these openings was discussed above in the context of the "plurality of openings" limitation of '501 patent claim 1. The evidence of record shows that this limitation is met.

f. Element [19E]: "one or more processors configured to receive one or more signals from at least one of the four photodiodes and output measurements responsive to the one or more signals, the measurements indicative of the oxygen saturation of the user"

There is no dispute that each of the Accused Products contain processors that receive signals from the photodiodes and output measurements of oxygen saturation. *See* CIB at 68. The relevant evidence was discussed above in the context of the "processors" limitation of '501 patent claim 1. The evidence of record shows that this limitation is met.

g. Element [20]: "further comprising a thermistor"

Claim 20 of the '502 patent depends from claim 19, further requiring a thermistor. There is no dispute that the Accused Products include a thermistor. *See* CIB at 68-69. Dr. Madisetti identified a of the Accused Products. Tr. (Madisetti) at 688:18-689:8; *see* CX-0026C (Apple Engineering Requirement Specification) at 31; CX-1548C (Apple Watch teardown photographs) at 37; CX-0059C (Apple Watch Series 7 Engineering Drawings) at 1-5. The evidence of record shows that this limitation is met.

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h. Element [21]: "wherein the one or more processors are further configured to receive a temperature signal from the thermistor and adjust operation of the user-worn device responsive to the temperature signal"

Claim 21 of the '502 patent depends from claim 20, further requiring that "the one or more processors are further configured to receive a temperature signal from the thermistor and adjust operation of the user device responsive to the temperature signal." There is no dispute that the Accused Products

See CIB at 69-70. Dr. Madisetti identified Apple documents and testimony showing that a processor in the Accused Products

Tr. (Madisetti) at 689:17-690:16 (citing CX-0100C (Apple Engineering Requirement Specification) at 8; see also CX-0281C (Block Dep. Tr.) at 62:3-64:17; CX-0283C (Charonneau-LeFort Dep. Tr.) at 78:4-79:18, 123:6-12; CX-0299C (Waydo Dep. Tr.) at 84:2-85:22; CX-0285C (Dua Dep. Tr.) at 139:1-15. The evidence of record shows that this limitation is met.

i. Element [22]: "wherein the plurality of emitters comprise at least four emitters, and wherein each of the plurality of emitters comprises a respective set of at least three LEDs"

Claim 22 of the '502 patent depends from claim 21, further requiring that "the plurality of emitters comprise at least four emitters, and wherein each of the plurality of emitters comprises a respective set of at least three LEDs." There is no dispute that the plurality of emitters in the Accused Products comprise four sets of three LEDs. *See* CIB at 70-71. The relevant evidence was discussed above in the context of the "LEDs" limitation of '501 patent claim 1. The evidence of record shows that this limitation is met.

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Accordingly, because each limitation of claims 19, 20, 21, and 22 are satisfied, the undersigned finds that the Accused Products infringe claim 22 of the '502 patent.

'502 Patent Claim 28

a. Element [28 preamble]: "A user-worn device configured to non-invasively measure an oxygen saturation of a user, the user worn device comprising:"

There is no dispute that the Accused Products meet the limitations of the preamble of '502 patent claim 28, which requires "[a] user-worn device configured to non-invasively measure an oxygen saturation of a user." *See* CIB at 72. The relevant evidence was discussed above in the context of the preamble of '501 patent claim 1. The evidence of record shows that this limitation is met.

b. Element [28A]: "a first set of light emitting diodes (LEDs), the first set of LEDs comprising at least an LED configured to emit light at a first wavelength and an LED configured to emit light at a second wavelength"

There is no dispute that each of the Accused Products contains four sets of LEDs, with each set containing three LEDs emitting light at different wavelengths. *See* CIB at 72. The relevant evidence was discussed above in the context of the "LEDs" limitation of '501 patent claim 1. The evidence of record shows that this limitation is met.

c. Element [28B]: "a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising at least an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength"

There is no dispute that each of the Accused Products contains four sets of LEDs, with each set containing three LEDs emitting light at different wavelengths. *See* CIB at 72. The relevant evidence was discussed above in the context of the "LEDs" limitation of '501 patent claim 1, and Dr. Block confirmed that the wavelengths in each of the LED groups is the same-

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containing one infrared LED, one red LED, and one green LED. See CX-0281C (Block Dep. Tr.) at 65:5-67:20. The evidence of record shows that this limitation is met.

> Element [28C]: "four photodiodes arranged in a quadrant d. configuration on an interior surface of the user-worn device and configured to receive light after at least a portion of the light has been attenuated by tissue of the user"

There is no dispute that each of the Accused Products contains four photodiodes arranged in a quadrant configuration receiving light that has been attenuated by tissue of the user. See CIB at 72-73. The relevant evidence was discussed above in the context of the "photodiodes" limitation of '501 patent claim 1, and Dr. Madisetti identified photographs of the sensor board of the Accused Products showing the quadrant configuration of the photodiodes. Tr. (Madisetti) at 692:3-16; CX-1548C. The evidence of record shows that this limitation is met.

> Element [28D]: "a thermistor configured to provide a temperature signal"

There is no dispute that each of the Accused Products contains a thermistor that provides a temperature signal. See CIB at 73. The relevant evidence was discussed above in the context of '502 patent claim 20. The evidence of record shows that this limitation is met.

> f. Element [28E]: "a protrusion arranged above the interior surface, the protrusion comprising: a convex surface"

There is no dispute that each of the Accused Products contains a protrusion comprising a convex surface, as discussed above in the context of the "protrusion" limitation of '501 patent claim 1. See CIB at 71. Apple disputes infringement of this limitation based on its erroneous proposed construction of the term "above." See RIB at 26-34; RRB at 21-29. These arguments have been rejected, however, as discussed above in the context of the "protrusion" limitation of '501 patent claim 1 and in the claim construction analysis above. See Part IV.D.1, supra.

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Accordingly, the undersigned finds that the Accused Products meet the limitation in '502 patent claim 28 requiring a "protrusion arranged over the interior surface."

g. Element [28F]: "a plurality of openings in the convex surface, extending through the protrusion, and aligned with the four photodiodes, each opening defined by an opaque surface configured to reduce light piping"

With respect to the "plurality of openings" limitation of '502 patent claim 28,

Complainants identify the same "openings" that are discussed above in the context of the

"plurality of openings" limitation of '501 patent claim 1. See CIB at 71. There is no dispute that
these openings are aligned with the four photodiodes. See id. Apple disputes infringement of
this limitation based on its erroneous proposed construction of the term "openings." See RIB at
34-39; RRB at 29-34. These arguments have been rejected, however, as discussed above in the
context of the "plurality of openings" limitation of '501 patent claim 1. Accordingly, the
undersigned finds that the Accused Products meet the limitation in '502 patent claim 28
requiring a "plurality of openings in the convex surface, extending through the protrusion, and
aligned with the four photodiodes." Further, there is no dispute that the Accused Products have
opaque surfaces surrounding the openings that are configured to reduce light piping, as discussed
above in the context of the "opaque lateral surface" limitation of '501 patent claim 1. See CIB at
71. Accordingly, the evidence shows that this limitation is met by the Accused Products.

h. Element [28G]: "a plurality of transmissive windows, each of the transmissive windows extending across a different one of the openings"

There is no dispute that each of the Accused Products contains transmissive windows extending across each of the identified openings. *See* CIB at 73. The evidence for the presence of transparent windows in these openings was discussed above in the context of the "plurality of

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openings" limitation of '501 patent claim 1. The evidence of record shows that this limitation is met.

i. Element [28H]: "at least one opaque wall extending between the interior surface and the protrusion, wherein at least the interior surface, the opaque wall and the protrusion form cavities, wherein the photodiodes are arranged on the interior surface within the cavities"

There is no dispute that each of the Accused Products contains an opaque wall between the interior surface and the protrusion that forms a cavity for the photodiodes. *See* CIB at 74. Dr. Madisetti identified the opaque wall in photographs of the Accused Products. Tr. (Madisetti) at 692:17-693:13; *see* CX-1646C (Complaint Exhibit 18) at 4; CX-0026C (Apple Engineering Requirement Specification) at 7-8, 30-32; CX-0059C (Apple Watch Series 7 Engineering Drawings) at 1-3; *see also* CX-0283C (Charbonneau-Lefort Dep. Tr.) at 87:5-8, 105:22-106:7. The evidence of record shows that this limitation is met.

j. Element [281]: "one or more processors configured to receive one or more signals from at least one of the photodiodes and calculate an oxygen saturation measurement of the user, the one or more processors further configured to receive the temperature signal"

There is no dispute that each of the Accused Products contains processors that receive signals from the photodiodes and output measurements of oxygen saturation, and there is no dispute that the processors receive a temperature signal. *See* CIB at 74. The relevant evidence was discussed above in the context of the "processors" limitations of '501 patent claim 1 and '502 patent claim 21. The evidence of record shows that this limitation is met.

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k. Element [28J]: "a network interface configured to wirelessly communicate the oxygen saturation measurement to at least one of a mobile phone or an electronic network"

There is no dispute that the Accused Products have a network interface that can wirelessly communicate oxygen saturation measurements to a mobile phone or electronic network. *See* CIB at 74-75. Dr. Madisetti identifies Bluetooth and Wi-Fi interfaces that communicate SpO2 measurements to an Apple iPhone. Tr. (Madisetti) at 693:14-694:11; *see* CX-0010 (Apple website) at 5; CX-1726 (Apple Watch Series 7 Technical Specifications) at 21. This operation of the Accused Products was confirmed by the testimony of Apple engineers. *See* CX-0299C (Waydo Dep. Tr.) at 74:20-75:17 (SpO2 measurements "stored in the HealthKit database on the Watch will also eventually make its way to the phone" via "Wi-Fi or Bluetooth"); CX-0285C (Dua) at 144:9-14 ("the heart rate along with the SpO2 that's measured at the same time are both communicated to the iPhone"). The evidence of record shows that this limitation is met.

 Element [28K]: "a user interface comprising a touch-screen display, wherein the user interface is configured to display indicia responsive to the oxygen saturation measurement of the user"

There is no dispute that the Accused Products have a touch-screen display that shows oxygen saturation measurements. *See* CIB at 75-76. Dr. Madisetti identified Apple documents showing that Apple Watches have touch-screen displays that can show an SpO2 measurement. Tr. (Madisetti) at 694:12-22 (citing CX-1407 at 3); *see also* CX-0281C (Block Dep. Tr. at 237:11-238:8); CX-0010 (Apple webpage). The evidence of record shows that this limitation is met.

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m. Element [28L]: "a storage device configured to at least temporarily store at least the measurement"

There is no dispute that the Accused Products store the blood oxygen measurement in memory. See CIB at 76. Apple engineers confirmed that the SpO2 values are stored in the memory of the Accused Products. See CX-0299C (Waydo Dep. Tr.) at 74:17-19; CX-0285C (Dua Dep. Tr.) at 131:8-15; see also CX-1726 at 1-2 (identifying memory in Apple Watch Series 7). The evidence of record shows that this limitation is met.

n. Element [28M]: "a strap configured to position the user-worn device on the user"

There is no dispute that the Accused Products have a strap. See CIB at 76. Dr. Madisetti identified a strap configured to hold the Accused Products in place on a user's wrist. Tr. (Madisetti) at 695:11-20; see CX-0010 (Apple website) at 4; CX-1726 (Apple Watch Series 7 Technical Specifications) at 3. The evidence of record shows that this limitation is met.

Accordingly, because each limitation of the claim is satisfied, the undersigned finds that the Accused Products infringe claim 28 of the '502 patent.

- 4. '648 Patent Claim 1210
 - a. Element [8 preamble]: "A user-worn device configured to noninvasively determine measurements of a physiological parameter of a user, the user-worn device comprising:"

There is no dispute that the Accused Products meet the limitations of the preamble of '648 patent claim 8, which requires "[a] user-worn device configured to non-invasively determine measurements of a physiological parameter of a user." See CIB at 77. The relevant

¹⁰ Because claim 12 of the '648 patent depends from claim 8, the infringement, technical prong and invalidity analyses address the limitations of claims 8 and 12. *See* CIB at xxix.

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evidence was discussed above in the context of the preamble of '501 patent claim 1. The evidence of record shows that this limitation is met.

b. Element [8A]: "a first set of light emitting diodes (LEDs), the first set comprising at least an LED configured to emit light at a first wavelength and at least an LED configured to emit light at a second wavelength"

There is no dispute that each of the Accused Products contains four sets of LEDs, with each set containing three LEDs emitting light at different wavelengths. *See* CIB at 78. The relevant evidence was discussed above in the context of the "LEDs" limitation of '501 patent claim 1. The evidence of record shows that this limitation is met.

c. Element [8B]: "a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength"

There is no dispute that each of the Accused Products contains four sets of LEDs, with each set containing three LEDs emitting light at different wavelengths. *See* CIB at 78. The relevant evidence was discussed above in the context of the "LEDs" limitation of '501 patent claim 1 and the "second set of LEDs" limitation of '502 patent claim 28. The evidence of record shows that this limitation is met.

d. Element [8C]: "four photodiodes"

There is no dispute that each of the Accused Products contains four photodiodes. See CIB at 78. The relevant evidence was discussed above in the context of the "photodiodes" limitation of '501 patent claim 1. The evidence of record shows that this limitation is met.

e. Element [8D]: "a protrusion comprising a convex surface, at least a portion of the protrusion comprising an opaque material"

There is no dispute that each of the Accused Products contains a protrusion comprising a convex surface, which includes a portion with opaque material. See CIB at 78. The relevant

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evidence was discussed above in the context of the "protrusion" and "openings" limitations of '501 patent claim 1. The evidence of record shows that this limitation is met.

f. Element [8E]: "a plurality of openings provided through the protrusion and the convex surface, the openings aligned with the photodiodes"

With respect to the "plurality of openings" limitation of '648 patent claim 8,

Complainants identify the same "openings" that are discussed above in the context of the
"plurality of openings" limitation of '501 patent claim 1. See CIB at 77. There is no dispute that
these openings are aligned with the four photodiodes. See id. Apple disputes infringement of
this limitation based on its erroneous proposed construction of the term "openings." See RIB at
34-39; RRB at 29-34. These arguments have been rejected, however, as discussed above in the
context of the "plurality of openings" limitation of '501 patent claim 1 and in the claim
construction analysis above. See Part IV.D.2, supra. Accordingly, the undersigned finds that the
Accused Products meet the limitation in '648 patent claim 8 requiring a "a plurality of openings
provided through the protrusion and the convex surface, the openings aligned with the
photodiodes."

g. Element [8F]: "a separate optically transparent window extending across each of the openings"

There is no dispute that each of the Accused Products contains optically transparent windows extending across each of the identified openings. *See* CIB at 78. The evidence for the presence of transparent windows in these openings was discussed above in the context of the "plurality of openings" limitation of '501 patent claim 1. The evidence of record shows that this limitation is met.

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h. Element [8G]: "one or more processors configured to receive one or more signals from at least one of the photodiodes and output measurements of a physiological parameter of a user"

There is no dispute that each of the Accused Products contains processors that receive signals from the photodiodes and output measurements of oxygen saturation. See CIB at 79. The relevant evidence was discussed above in the context of the "processors" limitation of '501 patent claim 1. The evidence of record shows that this limitation is met.

Element [8H]: "a housing"

There is no dispute that the Accused Products have a housing. See CIB at 79. Dr. Madisetti identified a photograph of the housing for the Accused Products. Tr. (Madisetti) at 697:17-24 (citing CX-1548C at 3). The evidence of record shows that this limitation is met.

> j. Element [8I]: "a strap configured to position the housing proximate tissue of the user when the device is worn"

There is no dispute that the Accused Products have a strap. See CIB at 80. The relevant evidence was discussed above in the context of the "strap" limitation of '502 patent claim 28. The evidence of record shows that this limitation is met.

> Element [12]: "the physiological parameter comprises oxygen k. or oxygen saturation"

There is no dispute that the Accused Products meet the limitations of '648 patent claim 12, which depends from claim 8 and requires that "the physiological parameter comprises oxygen or oxygen saturation." See CIB at 80. The relevant evidence was discussed above in the context of the preamble and the "physiological parameter" limitation of '501 patent claim 1. The evidence of record shows that this limitation is met.

Accordingly, because each of the limitations of claims 8 and 12 are satisfied, the undersigned finds that the Accused Products infringe claim 12 of the '648 patent.

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5. '648 Patent Claim 2411

a. Element [20 preamble]: "A user-worn device configured to non-invasively determine measurements of a user's tissue, the user-worn device comprising:"

There is no dispute that the Accused Products meet the limitations of the preamble of '648 patent claim 20, which requires "[a] user-worn device configured to non-invasively determine measurements of a user's tissue." *See* CIB at 81. The relevant evidence was discussed above in the context of the preamble of '501 patent claim 1. The evidence of record shows that this limitation is met.

b. Element [20A]: "a plurality of light emitting diodes (LEDs)"

There is no dispute that each of the Accused Products has LEDs. See CIB at 82. The relevant evidence was discussed above in the context of the "LEDs" limitation of '501 patent claim 1. The evidence of record shows that this limitation is met.

c. Element [20B]: "at least four photodiodes configured to receive light emitted by the LEDs, the four photodiodes being arranged to capture light at different quadrants of tissue of a user"

There is no dispute that each of the Accused Products contains four photodiodes arranged in quadrants. *See* CIB at 82. The relevant evidence was discussed above in the context of the "photodiodes" limitation of '501 patent claim 1 and the "photodiodes" limitation of '502 patent claim 28. The evidence of record shows that this limitation is met.

d. Element [20C]: "a protrusion comprising a convex surface"

There is no dispute that each of the Accused Products contains a protrusion comprising a convex surface. See CIB at 80-81. The relevant evidence was discussed above in the context of

¹¹ Because claim 24 of the '648 patent depends from claim 20, the infringement, technical prong and invalidity analyses address the limitations of claims 20 and 24. *See* CIB at xxix.

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the "protrusion" limitation of '501 patent claim 1. The evidence of record shows that this limitation is met.

e. Element [20D]: "a plurality of through holes, each through hole including a window and arranged over a different one of the at least four photodiodes"

With respect to the '648 patent claim 20 limitation requiring "a plurality of through holes," Complainants identify the holes in the protrusion that are discussed above in the context of the "plurality of openings" limitation of '501 patent claim 1. See CIB at 81. Apple disputes infringement of this limitation based on its erroneous proposed constructions of the claim terms "over" and "through holes." See RIB at 26-39; RRB at 21-34. These arguments have been rejected, however, as discussed above in the context of the "plurality of openings" limitation of '501 patent claim 1 and in the claim construction analysis above. See Part IV.D, supra.

Accordingly, the undersigned finds that the Accused Products meet the limitation in '648 patent claim 20 requiring a "a plurality of through holes, each through hole including a window and arranged over a different one of the at least four photodiodes."

f. Element [20E]: "one or more processors configured to receive one or more signals from at least one of the photodiodes and determine measurements of oxygen saturation of the user"

There is no dispute that each of the Accused Products contains processors that receive signals from the photodiodes and output measurements of oxygen saturation. *See* CIB at 82. The relevant evidence was discussed above in the context of the "processors" limitation of '501 patent claim 1. The evidence of record shows that this limitation is met.

g. Element [24]: "wherein the protrusion comprises opaque material configured to substantially prevent light piping"

Claim 24 of the '648 patent depends from claim 20, further requiring that "the protrusion comprises opaque material configured to substantially prevent light piping." There is no dispute

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that the identified protrusion in the Accused Products has a coating and ink that is configured to prevent light piping, as discussed above in the context of the "opaque lateral surface" limitation of '501 patent claim 1. *See* CIB at 82. The evidence of record shows that this limitation is met.

Accordingly, because each of the limitations of claims 20 and 24 are satisfied, the undersigned finds that the Accused Products infringe claim 24 of the '648 patent.

6. '648 Patent Claim 30

Claim 30 of the '648 patent depends from claim 20, further requiring that "the protrusion further comprises one or more chamfered edges." There is no dispute that the identified protrusion in the Accused Products has chamfered edges. See CIB at 82-83. Dr. Madisetti identified chamfered edges on engineering drawings for the Accused Products. Tr. (Madisetti) at 699:4-19; CX-0063C (Apple Watch Series 7 Engineering Drawings) at 2; see also CX-1548C (Apple Watch Series 7 Photographs) at 3; CX-0070C (Apple Watch Series 7 Engineering Drawings) at 1. The evidence of record shows that this limitation is met.

Accordingly, because each of the limitations of claims 20 and 30 are satisfied, the undersigned finds that the Accused Products infringe claim 30 of the '648 patent.

F. Domestic Industry—Technical prong

The domestic industry products that Complainants rely on for the Poeze patents are the RevA sensor (CPX-0052C), the RevD sensor (CPX-0058C), the RevE sensors (CPX-0019C, CPX-0020C, CPX-0065C), and the Masimo W1 (CPX-0146C). CIB at 26-35. Complainants allege that the RevA, RevD, RevE, and Masimo W1 devices practice claim 12 of the '501 patent and claims 12, 24, and 30 of the '648 patent; and that the RevD, RevE, and Masimo W1 devices

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practice claim 28 of the '502 patent. CIB at 85-117. For the reasons discussed below, the evidence shows, by a preponderance, that Complainants have satisfied the technical prong with respect to certain claims of the Poeze patents.

1. Consideration of Post-Complaint Evidence

As an initial matter, the parties dispute whether evidence of post-complaint activities can be considered in the context of the domestic industry requirement. *See* RIB at 18-21; RRB at 17-18, 154; CRB at 11-13.

Apple argues that the only evidence that should be considered with respect to the alleged domestic industry is evidence of activities that pre-date the filing of the complaint, citing Commission precedent requiring that satisfaction of the domestic industry requirement be assessed at the time of the complaint. RIB at 18-21. Apple relies on Certain Thermoplastic-Encapsulated Electric Motors, Components Thereof, and Products and Vehicles Containing the Same ("Thermoplastic-Encapsulated Electric Motors"), where the Commission stated that "[o]rdinarily, the relevant date at which to determine if the domestic industry requirement of section 337 is satisfied is the filing date of the complaint." Inv. No. 337-TA-1073, Comm'n Op. at 6-7, EDIS Doc. ID 684974 (Aug. 12, 2019). Apple argues that the date of the complaint is the relevant timeframe for evaluating the domestic industry, and that the Commission has held that it "will consider post-complaint evidence regarding domestic industry only in very specific circumstances, i.e., 'when a significant and unusual development has occurred after the complaint has been filed." Certain Collapsible Sockets for Mobile Electronic Devices and Components Thereof, Inv. No. 337-TA-1056, Comm'n Op. at 15 n.10, EDIS Doc. ID 649819 (July 9, 2018) (quoting Certain Television Sets, Television Receivers, Television Tuners, and

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Components Thereof, Inv. No. 337-TA-910, Comm'n Op. at 72, EDIS Doc. ID 568157 (Oct. 30, 2015)).

With respect to the technical prong, Complainants contend that post-complaint evidence can be considered in this investigation because the Masimo W1 (a post-complaint product) has been shown to practice claims of the asserted patents, in contrast to the post-complaint products in *Thermoplastic-Encapsulated Electric Motors*. CRB at 12. With respect to the economic prong, Complainants also distinguish the facts in *Thermoplastic-Encapsulated Electric Motors* because . *Id.*Complainants further argue that Masimo has made certain investments that represent significant and unusual developments, including investments in . , and the acquisition of Sound United. *See* Tr. (Scruggs) at 433:13-15; Tr. (McGavock) at 543:16-544:14, 545:3-17; Tr. (Al-Ali) at 323:18-324:25; Tr. (Muhsin) at 344:14-345:1; CX-1637 (Masimo 2021 Earnings Presentation) at 19-20; Tr. (Young) at 482:14-25.

Consistent with Commission precedent, evidence regarding Complainants' postcomplaint activities will not be considered with respect to the domestic industry in this investigation.

The Commission has held that, "as a general matter, the only activities that are relevant to the determination of whether a domestic industry exists or is in the process of being established are those that occurred before the complaint was filed." *Certain Video Game Systems and Controllers*, Inv. No. 337-TA-743, Comm'n Op., 2012 WL 13171643, at *3 (Jan. 20, 2012). However, "in appropriate situations, based on the specific facts and circumstances of an investigation, the Commission may consider activities and investments beyond the filing of the

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complaint." *Id.* ¹² The Commission has held that such "facts and circumstances" may be shown by "a significant and unusual development" such as circumstances pertaining to "bankruptcy, a change in patent ownership, manufacturing, or licensing activity." *Certain Television Sets*, *Television Receivers, Television Tuners, and Components Thereof*, Inv. No. 337-TA-910, Comm'n Op., 2015 WL 6755093 (Oct. 30, 2015). Where there has been no showing of significant and unusual developments, the Commission has held that it would be error to "consider[] evidence as of the close of discovery, rather than as of the complaint filing date." *Certain Televisions, Remote Controls, and Components Thereof*, Inv. No. 337-TA-1263, Comm'n Op., 2022 WL 17486245, at *13 (Nov. 30, 2022) ("*Certain Televisions*").

Complainants have not made a showing of significant and unusual developments in the present investigation. Complainants rely on developments with respect to the manufacturing of "Masimo Watch" products, CIB at 289-90, but to the extent that the Commission has considered post-complaint evidence due to unusual developments regarding manufacturing, this has been in circumstances involving the cessation of domestic manufacturing. See, e.g., Certain Video Graphics Display Controllers, and Products Containing Same, Inv. No. 337-TA-412, Initial Determination at 12-13, EDIS Doc. ID 172529 (May 17, 1999) (unreviewed in relevant part); Certain Variable Speed Wind Turbines and Components Thereof, Inv. No. 337-TA-376,

¹² The Federal Circuit has similarly affirmed the Commission's use of the complaint's filing date for assessing domestic industry under the facts and circumstances of the cases at issue. *See Bally/Midway Mfg. v. U.S. Int'l Trade Comm'n*, 714 F.2d 1117, 1120 (Fed Cir. 1983) (holding that, "under the circumstances of this case," the proper date for assessing the domestic "industry" was the filing date of the complaint, where a different position would undercut the purposes of Section 337); *Motiva, LLC v. Int'l Trade Comm'n*, 716 F.3d 596, 601 n.6 (Fed. Cir. 2013) (affirming Commission's use of the complaint's filing date as the relevant date for the domestic industry determination).

¹³ Apple argues that Complainants have waived any contention regarding "significant and unusual developments" because this argument was not raised in Complainants' pre-hearing brief. *See* RRB at 154. Complainants did not waive this argument. *See* CPHB at 229-231.

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Comm'n Op. 4, 10-13, EDIS Doc. ID 44138 (Aug. 21, 1997). Masimo's post-complaint progress towards the manufacture of "Masimo Watch" products appears to be consistent with Masimo's pre-complaint plans and projections for these products—there is nothing significant or unusual about these developments. *See* RIB at 19. Accordingly, post-complaint evidence regarding the alleged domestic industry will not be considered. *Cf. Certain Televisions*, 2022 WL 17486245, Comm'n Op. at *13 (holding that, in the context of considering whether the technical prong of the domestic industry had been shown, the ID erred to the extent post-complaint evidence was considered). ¹⁴

Masimo's asserted pre-complaint domestic industry products are the RevA (CPX-0052C), RevD (CPX-0058C), and RevE prototypes (CPX-0019C, CPX-0020C, CPX-0065C).

There is no dispute that the RevA and RevD sensors were made before the filing of the complaint—Mr. Scruggs explained that Masimo built the RevA sensor in November 2020, and the RevD sensor in April 2021. Tr. (Scruggs) at 396:2-13, 397:7-24. Masimo contends that two of the RevE prototypes were created pre-complaint. *See* CRB at 31-32. 15

The undersigned will not consider any evidence regarding the Masimo W1 product, because this product made in December 2021, several months after the complaint was filed. *See* Tr. (Kiani) at 124:5-24; Tr. (Scruggs) at 398:24-399:400:2.

¹⁴ The underlying Initial Determination reviewed by the Commission, like the investigation here, included a claim for a domestic industry in the process of being established. *See Certain Televisions, Remote Controls, and Components Thereof*, Inv. No. 337-TA-1263, Initial Determination, at 89-92, 144-145 (June 28, 2022) (EDIS Doc. ID 775506).

¹⁵ Apple contends that the software installed on the RevD sensor has a most recent date of July 30, 2021, and that the software installed on the RevE sensors was not loaded until September and October 2021, with an earliest "known date" of July 9, 2021—after the filing of the complaint. *See* RIB at 42-43. This issue is discussed *infra* in the context of whether a domestic industry existed at the time of the complaint.

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A limitation-by-limitation analysis for the RevA, RevD, and RevE devices is set forth below.

2. '501 Patent Claim 12

a. Element [1 preamble]: "A user-worn device configured to noninvasively measure a physiological parameter of a user, the user-worn device comprising:"

The preamble of '501 patent claim 1 requires "[a] user-worn device configured to noninvasively measure a physiological parameter of a user." Complainants submit that the RevA, RevD, and RevE devices meet this limitation because they are configured to measure the oxygen saturation and pulse rate of a user. CIB at 86-87; see also CIB at 30-35. Complainants rely on testimony from Mr. Scruggs and Mr. Muhsin describing the functionality of each of the Masimo devices. Tr. (Scruggs) at 407:22-408:4, 410:1-4, 405:8-406:11; Tr. (Muhsin) at 346:6-15. Dr. Madisetti observed a demonstration of the RevA, RevD, and RevE by Mr. Scruggs and determined that these devices each calculate oxygen saturation. Tr. (Madisetti) at 715:20-716:21; CDX-0011C.054. Mr. Al-Ali described internal testing of the oxygen saturation measurements of Masimo's prototype sensors that was presented in October 2020. Tr. (Al-Ali) at 272:16-277:13; CX-0378C at 32. He described this presentation as relating to a sensor with a design consistent with the RevA device (CPX-0052C). See Tr. (Al-Ali) at 270:17-22 (referencing id. at 260:11-25:14 (discussing CX-0375C; CPX-0052C)). He also described testing of other prototype Masimo Watch devices in early 2021. Tr. (Al-Ali) at 265:15-268:21, 276:12-278:3; CX-0433C. Mr. Al-Ali further described testing of RevE devices in June 2021. Tr. (Al-Ali) at 316:2-317:20; CX-0494C. Masimo submits that the test results for the domestic industry products show a degree of accuracy that is consistent with FDA guidance. CIB at 85 (citing CX-0269).

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Apple argues that Complainants have not met their burden to show that any of the domestic industry products measure oxygen saturation. RIB at 46-52. Apple submits that Complainants failed to identify the source code in the domestic industry products that calculates any physiological parameter. *Id.* at 47-48; *see* Tr. (Sarrafzadeh) at 1124:24-1125:11. Apple's experts testified that their observations of demonstrations of the domestic industry products were insufficient to determine whether oxygen saturation or pulse rate were being measured. Tr. (Warren) at 1254:8-1256:25; Tr. (Sarrafzadeh) at 1122:20-1126:20. They further testified that certain measurements of blood oxygen relied upon by Complainants were "inconsistent" with reference measurements from another Masimo device. Tr. (Sarrafzadeh) at 1126:7-20; Tr. (Warren) at 1256:2-25; RDX-0008.149C.

With respect to the RevA and RevD sensors, Apple disputes whether these are "user-worn" devices, because the devices were produced without a strap or any other means for being worn by a user. RIB at 45-46. Complainants submit that each of these sensors includes mechanisms for attaching a strap, and Mr. Scruggs testified that they each had straps "at one point in time." Tr. (Scruggs) at 405:8-406:3, 406:23-407:18; CIB at 89.

In consideration of this evidence, the undersigned finds that Complainants have shown by a preponderance of the evidence that the RevA, RevD, and RevE devices measure blood oxygen saturation. The testimony of Masimo's witnesses is credible regarding the design and testing of these products with respect to measuring blood oxygen, and is supported by the results of the testing described in Masimo's documents. In particular, Mr. Al-Ali explicitly identified testing of blood oxygen functionality conducted in 2020 using prototype designs consistent with the RevA sensor, additional testing in the timeframe of the RevD devices in early 2021, and further testing of RevE devices in June 2021. Tr. (Al-Ali) at 260:11-25:14, 265:15-268:21, 270:17-22,

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276:12-278:3, 315:16-316:18; CX-0375C; CX-0378C; CX-0433C; CX-0494C.

Dr. Madisetti observed a demonstration of the RevA, RevD, and RevE by Mr. Scruggs and determined that these devices each calculate oxygen saturation. Tr. (Madisetti) at 715:20-716:21; CDX-0011C.054.

Apple's experts also attended a demonstration of the RevA, RevD, and RevE by Mr. Scruggs, although their observations were inconclusive. Tr. (Warren) at 1254:4-1256:25; Tr. (Sarrafzadeh) at 1122:20-1126:20; RDX-0007C.154; RX-1470; see Tr. (Warren) at 1258:9-17 ("My opinion is that these DI articles do not implement the functionality in that's in the claims, because I was not able to establish that they were producing physiological parameters.").

The testimony of Mr. Ali-Ali regarding Masimo's internal testing, together with Dr. Madisetti's testimony, credibly indicate that Masimo's sensors are configured to make oxygen saturation measurements. See Tr. (Ali-Ali) at 272:16-275:12, 276:12-278:3, 318:15-22;

that, Mr. Ali-Ali explained, provided measurements "well within acceptable numbers for a hospital product." *See* Tr. (Ali-Ali) at 274:11-275:3. Apple argues that this testing is not clearly linked to the specific domestic industry prototypes produced, CRB at 41-42, but the timing of these testing results matches with the development of the RevA, RevD, and RevE devices, and the fact that Masimo was able to test the blood oxygen functionality of multiple prototypes during this time is strong circumstantial evidence that the RevA, RevD, and RevE devices were capable of measuring blood oxygen, particularly given the evidence that these devices were not separate products, but part of an iterative design process. *See, e.g.*, Tr. (Scruggs) at 394:13-398:23. Moreover, as discussed *infra*, a domestic industry in the process of being established does not require the current existence of a physical article. Thus, this testing also strongly supports a finding that Masimo had, at the time of filing the complaint, taken necessary tangible steps to develop a product that will practice this limitation of the patent and a significant likelihood of success in doing so.

¹⁷ Apple cites the fact that Dr. Madisetti was unable to identify the correct Masimo source code at hearing. *See* CRB at 33-34. This does not undercut the demonstrated evidence that Masimo tested its devices to measure blood oxygen saturation.

¹⁸ Apple's experts identified differences in the oxygen saturation measurements of a commercially available pulse oximeter in comparison to the Masimo W1, but this post-complaint device is not being considered as part of the asserted domestic industry. *See* RDX-0008.149C. Moreover, the variation in the measurements appears to be consistent with FDA guidance regarding pulse oximetry—an FDA document identified by Complainants states: "For example, if an FDA-cleared pulse oximeter reads 90%, then the true oxygen saturation in the blood is generally between 86%-94%." CX-0269 (FDA Safety Communication) at 4.

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CX-0378C at 32; CX-0494C; Tr. (Madisetti) at 715:20-716:20; CDX-0011C.054. The evidence of record is sufficient to show, by a preponderance, that the RevA, RevD, and RevE sensors measure blood oxygen.

With respect to the "user-worn" limitation, there is no dispute that the RevE sensors have straps that allow these devices to be worn. *See* Tr. (Scruggs) at 408:20-409:14; CPX-0019C; CPX-0020C; CPX-0065C. The RevA and RevD sensors produced in discovery do not have straps, but these devices have attachment mechanisms for a strap, and Mr. Scruggs testified that these devices had straps "at one point in time." Tr. (Scruggs) at 405:8-406:3, 406:23-407:18, 460:13-17. Moreover, as discussed above, Mr. Al-Ali described testing relating to the Masimo's RevA and RevD sensors in the fall of 2020 and early 2021. Tr. (Al-Ali) at 260:11-25:14, 265:15-268:21, 270:17-22, 276:12-278:3. His description of this testing suggests that the devices were "user-worn." *See Id.* at 278:5-13 (describing placement of devices on user's wrist). The evidence is sufficient to show, by a preponderance, that the RevA, RevD, and RevE sensors meet the "user-worn" limitation.

Accordingly, a preponderance of the evidence of record shows that the RevA, RevD, and RevE sensors meet the limitations of the preamble of '501 patent claim 1.

b. Element [1A]: "at least three light emitting diodes (LEDs)"

There is no dispute that the RevA, RevD, and RevE devices each contain a sensor module with at least three LEDs. *See* CIB at 89-91; RIB at 45-54. Dr. Madisetti identified two clusters of LEDs in each of these devices, with each cluster containing four or five LEDs. Tr. (Madisetti) at 711:14-712:4, 712:20-713:15; CDX-0011C.09 (citing CX-1111C (RevA CAD); CX-1124C

¹⁹ The testing data for the sensor consistent with the RevA device includes "Motion Analysis," including "Walking/Running." CX-0378C at 27.

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(RevD CAD); CX-1125C (RevE CAD); see CPX-0052C (RevA); CPX-0058C (Rev D); CPX-0019C, CPX-0020C, CPX-0065C (RevE). The evidence of record shows that this limitation is met by the RevA, RevD, and RevE devices.

c. Element [1B]: "at least three photodiodes arranged on an interior surface of the user-worn device and configured to receive light attenuated by tissue of the user"

Dr. Madisetti identified at least three photodiodes on an interior surface in each of the RevA, RevD, and RevE devices. Tr. (Madisetti) at 712:5-19. He relied on photographs and schematics of the devices to identify the photodiodes. *Id.*; CDX-0011C.050 (for RevA citing CPX-0052C; CX-0661C (photo)); CX-0473C (schematic) at 1, 3; CX-1111C (CAD) at 3, 5, 6; for RevD citing CPX-0058C; CX-0389C (schematic) at 1, 3; CX-1124C (CAD) at 3-4, 8; for RevE citing CPX-0019C, CPX-0020C, CPX-0065C; CX-0653C, CX-0655C, CX-0676C (photos); CX-0390C (schematic) at 1, 3; CX-1125C (CAD) at 2, 6, 7); *see generally* CIB at 91-92.

Apple argues that the evidence produced by Complainants is insufficient to show that these devices each have at least three photodiodes, because these elements are not visible from the outside of the devices and the schematics and technical drawings are allegedly unreliable.

RIB at 52-54. Mr. Scruggs admitted that there were certain discrepancies between Masimo's CAD files and the actual RevA, RevD, and RevE sensors, recognizing that the devices represented "what we were able to manufacture at the time." RX-1209C (Scruggs Dep. Tr.) at 91:18-92:24; see also Tr. (Scruggs) at 465:2-467:18 (confirming "there are some differences" between the CAD files and the prototype products). Dr. Warren was unable to confirm whether the devices had photodiodes through a visual inspection. Tr. (Warren) at 1259:12-23.

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In consideration of the parties' arguments, the undersigned finds that Complainants have shown by a preponderance of the evidence that the RevA, RevD, and RevE devices each have at least three photodiodes meeting this claim limitation. Although there are some discrepancies between the physical prototypes and Masimo's schematics and technical drawings, there is no evidence that the layout of the photodiodes is inaccurate. Mr. Scruggs testified that "the essential meat and potatoes stuff, like the sensor, it's very accurately reflected" by the CAD drawings, because "that's very important for the devices." Tr. (Scruggs) at 467:2-7, 477:9-478:8; see also Tr. (Al-Ali) at 313:144-314:7 (confirming the accuracy of the CAD drawings for the RevE sensors).

Accordingly, the evidence shows, by a preponderance, that each of the RevA, RevD, and RevE devices meet the "at least three photodiodes" limitation of '501 patent claim 1.

d. Element [1C]: "a protrusion arranged over the interior surface, the protrusion comprising a convex surface"

There is no dispute that the RevA, RevD, and RevE devices each contain a convex protrusion. *See* CIB at 92-93. Dr. Madisetti identified convex protrusions in each of these devices, relying on photographs and the physical devices. Tr. (Madisetti) at 713:16-714:7; CDX-0011C.051 (citing CX-0813C (RevA); CX-0815C (RevD); CX-0812C (RevE); *see* CPX-0052C (RevA); CPX-0058C (Rev D); CPX-0019C, CPX-0020C, CPX-0065C (RevE). The evidence of record shows that this limitation is met by the RevA, RevD, and RevE devices.

e. Element [1D]: "a plurality of openings extending through the protrusion and positioned over the three photodiodes"

In the convex protrusion of the RevA, RevD, and RevE devices, Dr. Madisetti identified openings with transparent windows, relying on technical drawings and the physical devices. Tr. (Madisetti) at 714:8-24; CDX-0011C.052 (citing CX-1111C (RevA); CX-1124C (RevD); CX-

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1125C (RevE)); see CPX-0052C (RevA); CPX-0058C (Rev D); CPX-0019C, CPX-0020C, CPX-0065C (RevE); CIB at 93-95. Apple argues that these features are not "openings," referencing its non-infringement arguments for this limitation. RRB at 43. This argument is inconsistent with the claim construction for "openings" adopted above, and accordingly, the evidence shows that the RevA, RevD, and RevE devices meet the plurality of openings" limitation of '501 patent claim 1.

f. Element [1E]: "the openings each comprising an opaque lateral surface, the plurality of openings configured to allow light to reach the photodiodes, the opaque lateral surface configured to avoid light piping through the protrusion"

Mr. Scruggs described a "light barrier" present in the RevA, RevD, and RevE devices that is a "black feature that surrounds the emitters so it separates the LEDs from the photodiodes." Tr. (Scruggs) at 400:3-24; CDX-005C.002. He explained that the light barrier was configured "so that light would travel only into the skin and . . . to minimize light traveling within the sensor." *Id.* Dr. Madisetti identified these features in technical drawings for the RevA, RevD, and RevE devices and testified that these were opaque lateral surfaces configured to allow light to reach the photodiodes and to avoid light piping through the protrusion. Tr. (Madisetti) at 714:25-19; CDX-0011C.053 (citing CX-1111C (RevA); CX-1124C (RevD); CX-1125C (RevE)).

Apple argues that the evidence produced by Complainants is insufficient to show that these devices have the claimed opaque lateral surfaces, because these features are not visible from the outside of the devices, and the schematics and technical drawings are allegedly unreliable. RIB at 52-54; RRB at 43-44. For the same reasons discussed above in the context of the "at least three photodiodes" limitation, Complainants have shown by a preponderance of the evidence that the RevA, RevD, and RevE devices each have opaque lateral surfaces meeting this

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claim limitation. The undersigned finds Mr. Scruggs's testimony regarding these features to be credible and Masimo's CAD drawings to be reliable with respect to these features.

Accordingly, the evidence shows by a preponderance that each of the RevA, RevD, and RevE devices meet the "opaque lateral surface" limitation of '501 patent claim 1.

g. Element [1F]: "one or more processors configured to receive one or more signals from the photodiodes and calculate a measurement of the physiological parameter of the user"

Dr. Madisetti identifies processors in the RevA, RevD, and RevE devices that receive signals from photodiodes and calculate oxygen saturation. Tr. (Madisetti) at 715:20-716:21. Dr. Madisetti relies on documentation for each of these products. *Id.*; CDX-0011C.054 (for RevA: CX-0701C at 2, CPX-012C, and CX-0836C at 4; for RevD: CX-0710C at 2-3, CX-1062C at 48, and CX-1074C; for RevE: CX-0705C at 2-3, CX-1062C at 30, 35). Mr. Scruggs described the measurement of oxygen saturation and pulse rate in each iteration of the Masimo Watch. Tr. (Scruggs) at 393:17-394:3. He described the sensor board of the RevA device including two processors on the sensor board responsible for calculating the pulse oximetry measurement. *Id.* at 406:4-11. He also identified two processors on the sensor board of the RevD device. *Id.* at 408:11-19.

As discussed above in the context of the preamble, Apple argues that Complainants have not met their burden to show that any of the domestic industry products measure oxygen saturation. RIB at 46-52. For the reasons discussed above, however, the undersigned finds that Complainants have met their burden to show, by a preponderance, that the RevA, RevD, and RevE devices calculate oxygen saturation. The record evidence further shows, by a preponderance, that the RevA, RevD, and RevE each contain processors for receiving signals from the photodiodes and calculating oxygen saturation.

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Accordingly, the evidence shows that each of the RevA, RevD, and RevE devices meet the "one or more processors" limitation of '501 patent claim 1.

h. Element [12]: "wherein the convex surface of the protrusion is an outermost surface configured to contact the tissue of the user and conform the tissue into a concave shape"

Claim 12 of the '501 patent depends from claim 1, further requiring that "the convex surface of the protrusion is an outermost surface configured to contact the tissue of the user and conform the tissue into a concave shape." There is no dispute that this limitation is practiced by the RevA, RevD, and RevE devices. *See* CIB at 102. As discussed above, Dr. Madisetti identified a convex protrusion in these products, and his analysis confirms that the protrusion is designed to contact a user's wrist and conform the skin into a concave shape. *See* Tr. (Madisetti) at 716:24-717:13; CDX-0011C.055 (citing CX-0813C (RevA); CX-0815C (RevD); CX-0812C (RevE)).

Accordingly, because each limitation of claims 1 and 12 are satisfied by a preponderance of the evidence, the undersigned finds that the RevA, RevD, and RevE devices practice claim 12 of the '501 patent.

3. '502 Patent Claim 28

a. Element [28 preamble]: "A user-worn device configured to non-invasively measure an oxygen saturation of a user, the user worn device comprising:"

The preamble of '502 patent claim 28 requires "[a] user-worn device configured to non-invasively measure an oxygen saturation of a user." The parties' disputes with respect to this preamble are the same as those addressed above in the context of the preamble of '501 patent claim 1. See CIB at 102; RIB at 54. As discussed above in the context of the preamble of '501

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patent claim 1, Complainants have shown by a preponderance of the evidence that the RevD and RevE devices are user-worn devices that measure blood oxygen saturation, meeting the limitations of the preamble of '502 patent claim 28.²⁰

b. Element [28A]: "a first set of light emitting diodes (LEDs), the first set of LEDs comprising at least an LED configured to emit light at a first wavelength and an LED configured to emit light at a second wavelength"

There is no dispute that the RevD and RevE devices contain LEDs, as discussed above in the context of the "LEDs" limitation of '501 patent claim 1. See CIB at 103. Dr. Madisetti identified two clusters of LEDs in each of these devices, with each cluster containing four or five LEDs. Tr. (Madisetti) at 711:14-712:4, 712:20-713:15; CDX-0011C.09 (citing CX-1111C (RevA CAD); CX-1124C (RevD CAD); CX-1125C (RevE CAD); CX-1128C (Masimo W1 CAD); see CPX-0052C (RevA); CPX-0058C (Rev D); CPX-0019C, CPX-0020C, CPX-0065C (RevE)). Complainants rely on the testimony of Mr. Scruggs with respect to the wavelengths of light in these LEDs, identifying clusters of four LEDs in the RevD and RevE devices with wavelengths of Tr. (Scruggs) at 406:23-407:18, 408:20-409:14. Apple argues that Dr. Madisetti did not identify any evidence of these wavelengths and that the arrangement of the LEDs could not be confirmed by a visual inspection, RIB at 55, but Mr. Scruggs's testimony and Masimo's schematics are sufficient to show, by a preponderance, that the RevD and RevE devices meet this limitation of '502 patent claim 28.

²⁰ Complainants do not assert that the RevA device practices claim 28 of the '502 patent. See CIB at 102-112.

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c. Element [28B]: "a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising at least an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength"

As discussed above in the context of the "LEDs" limitation of '501 patent claim 1 and the "first set of LEDs" limitation of '502 patent claim 28, the evidence shows that the RevD and RevE devices each have two separate clusters of LEDs, and Mr. Scruggs described these clusters as having the same sets of wavelengths. *See* Tr. (Scruggs) at 406:23-407:18, 408:20-409:14, 410:5-24. Accordingly, the evidence shows, by a preponderance, that the RevD and RevE devices meet the "second set of LEDs" limitation of '502 patent claim 28.

d. Element [28C]: "four photodiodes arranged in a quadrant configuration on an interior surface of the user-worn device and configured to receive light after at least a portion of the light has been attenuated by tissue of the user"

With respect to the "four photodiodes" limitation of '502 patent claim 28, Complainants rely on the same evidence discussed above in the context of the "at least three photodiodes" limitation of '501 patent claim 1. See CIB at 103-04. Complainants identify a "quadrant configuration" in schematics of these products that were reviewed by Dr. Madisetti. Id. (citing CDX-0011C.050; CX-1111C; CX-1124C; CX-1125C; CX-1128C). Apple argues that Complainants' evidence with respect to this limitation is unreliable, see RIB at 54-55, but for the same reasons discussed above in the context of the "at least three photodiodes" limitation of '501 patent claim 1, the undersigned finds that Complainants have shown by a preponderance of the evidence that the RevD and RevE devices each have four photodiodes arranged in a quadrant configuration that meet this claim limitation.

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e. Element [28D]: "a thermistor configured to provide a temperature signal"

Dr. Madisetti identified thermistors in the RevD and RevE devices, relying on schematics and technical drawings. Tr. (Madisetti) at 720:21-721:5; CDX-0011C.059 (for RevD citing CX-1124C (CAD) at 3, 8; CX-0536C (schematic) at 1, 3; CX-0710C (schematic) at 3, 7; for RevE citing CX-1125C (CAD) at 2, 7; CX-0705C (schematic) at 3, 7; CX-0390C (schematic) at 3).

Mr. Scruggs identified two thermistors in the RevD and RevE devices. Tr. (Scruggs) at 406:23-407:18 (RevD), 408:20-409:14 (RevE); see generally CIB at 104-106.

Apple argues that the evidence produced by Complainants is insufficient to show that these devices have the claimed thermistors, because these features are not visible from the outside of the devices, and the schematics and technical drawings are allegedly unreliable. RIB at 54-55. For the same reasons discussed above in the context of the photodiode limitations of '501 patent claim 1, the undersigned finds Mr. Scruggs's testimony regarding these features to be credible and Masimo's CAD drawings to be reliable with respect to these features.

Accordingly, the undersigned finds that each of the RevD and RevE devices meet the "thermistor" limitation of '502 patent claim 28.

f. Element [28E]: "a protrusion arranged above the interior surface, the protrusion comprising: a convex surface"

There is no dispute that each of the RevD and RevE devices contain a protrusion comprising a convex surface that is arranged above the interior surface, as discussed above in the context of the "protrusion" limitation of '501 patent claim 1. *See* CIB at 106. The evidence shows, by a preponderance, that this limitation is met by the RevD and RevE devices.

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g. Element [28F]: "a plurality of openings in the convex surface, extending through the protrusion, and aligned with the four photodiodes, each opening defined by an opaque surface configured to reduce light piping"

There is no dispute that each of the RevD and RevE devices have a "plurality of openings" extending through the protrusion and aligned with the photodiodes, as discussed above in the context of the "plurality of openings" limitation of '501 patent claim 1, and these openings are defined by opaque surfaces, as discussed above in the context of the "opaque lateral surface" limitation of '501 patent claim 1. *See* CIB at 106. The evidence shows, by a preponderance, that this limitation is met by the RevD and RevE devices.

h. Element [28G]: "a plurality of transmissive windows, each of the transmissive windows extending across a different one of the openings"

There is no dispute that each of the RevD and RevE devices have a "plurality of transmissive windows," as discussed above in the context of the "plurality of openings" limitation of '501 patent claim 1. *See* CIB at 106-07. The evidence shows, by a preponderance, that this limitation is met by the RevD and RevE devices.

i. Element [28H]: "at least one opaque wall extending between the interior surface and the protrusion, wherein at least the interior surface, the opaque wall and the protrusion form cavities, wherein the photodiodes are arranged on the interior surface within the cavities"

There is no dispute that each of the RevD and RevE devices contain an opaque wall between the interior surface and the protrusion, as discussed above in the context of the "opaque lateral surface" limitation of '501 patent claim 1. *See* CIB at 107-08. Dr. Madisetti further identifies cavities formed by the opaque wall and the protrusion, relying on schematics and technical drawings. Tr. (Madisetti) at 721:6-25; CDX-0011C.060 (for RevD citing CX-1124C (CAD); CX-0666C (schematic); for RevE citing CX-1125C (CAD); CX-1038C (schematic)).

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The evidence shows, by a preponderance, that this limitation is met by the RevD and RevE devices.

j. Element [28I]: "one or more processors configured to receive one or more signals from at least one of the photodiodes and calculate an oxygen saturation measurement of the user, the one or more processors further configured to receive the temperature signal"

There is no dispute that each of the RevD and RevE devices contain processors that receive signals from the photodiodes, as discussed above in the context of the "processors" limitation of '501 patent claim 1. See CIB at 108. Apple disputes whether these processors calculate oxygen saturation, RIB at 54, but as discussed above in the context of the preamble of the '501 patent claim 1, a preponderance of the evidence shows that the RevD and RevE devices measure and calculate oxygen saturation. Moreover, there is no dispute that the processors receive a temperature signal, as discussed above in the context of the "thermistor" limitation. See id. at 104-108. The evidence shows, by a preponderance, that this limitation is met by the RevD and RevE devices.

k. Element [28J]: "a network interface configured to wirelessly communicate the oxygen saturation measurement to at least one of a mobile phone or an electronic network"

There is no dispute that the RevD and RevE devices contain network interfaces that can communicate with a mobile device via Bluetooth. *See* CIB at 108-110. Dr. Madisetti identified evidence that these devices have a network interface. Tr. (Madisetti) at 722:1-24; CDX-0011C.061 (citing CX-0709C (RevD and RevE sensor board schematic); CX-0836C (RevE demonstration photographs) at 9, 12, 13). Mr. Scruggs described the wireless communication capability of the RevD and RevE devices. Tr. (Scruggs) at 406:23-407:18, 408:20-409:14. The evidence shows, by a preponderance, that this limitation is met by the RevD and RevE devices.

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 Element [28K]: "a user interface comprising a touch-screen display, wherein the user interface is configured to display indicia responsive to the oxygen saturation measurement of the user"

There is no dispute that the RevD and RevE devices have a touch-screen display that shows oxygen saturation measurements. *See* CIB at 111. Dr. Madisetti identified evidence that these devices have touch-screen displays that can show an SpO2 measurement. Tr. (Madisetti) at 722:1-24; CDX-0011C.061 (citing CPX-058C (RevD device); CX-1062C (photographs); CPX-019C, CPX-020C, CPX-065C (RevE devices); CX-1068C, CX-1069C, CX-1072C (RevE device videos)). The evidence shows, by a preponderance, that this limitation is met by the RevD and RevE devices.

m. Element [28L]: "a storage device configured to at least temporarily store at least the measurement"

There is no dispute that the RevD and RevE devices store the blood oxygen measurement in memory. See CIB at 111. Dr. Madisetti identified evidence that these devices have memory to store the SpO2 measurement. Tr. (Madisetti) at 722:1-24; CDX-001C.061 (citing CX-0709C (RevD and RevE sensor board schematic)). The evidence shows, by a preponderance, that this limitation is met by the RevD and RevE devices.

n. Element [28M]: "a strap configured to position the user-worn device on the user"

There is no dispute that the RevE have straps for a user's wrist. *See* CIB at 112; CPX-019C, CPX-020C, CPX-065C. With respect to the RevD device, Complainants identify a mechanism for attaching a strap and rely on Mr. Scruggs's testimony that it had a strap "at some point." *See* Tr. (Scruggs) at 406:23-407:18. As discussed above in the context of the preamble of '501 patent claim 1, the undersigned finds that a preponderance of the evidence shows that the RevD device also had a strap.

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Accordingly, because each limitation of the claim is satisfied, the undersigned finds that the RevD and RevE products practice claim 28 of the '502 patent.

4. '648 Patent Claim 12

a. Element [8 preamble]: "A user-worn device configured to noninvasively determine measurements of a physiological parameter of a user, the user-worn device comprising:"

The preamble of '648 patent claim 8 requires "[a] user-worn device configured to non-invasively determine measurements of a physiological parameter of a user." The parties' disputes with respect to this preamble are the same as those addressed above in the context of the preamble of '501 patent claim 1. *See* CIB at 112; RIB at 55-56. As discussed above in the context of the preamble of '501 patent claim 1, the undersigned finds that Complainants have shown by a preponderance of the evidence that the RevA, RevD, and RevE devices are user-worn devices that measure blood oxygen saturation, meeting the limitations of the preamble of '502 patent claim 28.

b. Element [8A]: "a first set of light emitting diodes (LEDs), the first set comprising at least an LED configured to emit light at a first wavelength and at least an LED configured to emit light at a second wavelength"

There is no dispute that the RevA, RevD, and RevE devices each contain LEDs, as discussed above in the context of the "LEDs" limitation of '501 patent claim 1. See CIB at 112-13. Apple disputes whether the LEDs meet each of these limitations, see RIB at 56, but as discussed in the context of the "first set of LEDs" limitation of '502 patent claim 28, the evidence shows that the LEDs are arranged in clusters in the RevD and RevE devices and have a first and second wavelength. In addition, the evidence shows that the LEDs in the RevA device

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have wavelengths that are the same as the RevD and RevE devices, as discussed by Mr. Scruggs. See Tr. (Scruggs) at 405:8-406:3.

c. Element [8B]: "a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength"

There is no dispute that the RevA, RevD, and RevE devices each contain clusters of LEDs, as discussed above in the context of the "LEDs" limitation of '501 patent claim 1. See CIB at 112-13. Moreover, the undersigned finds that there is a second set of LEDs in the RevD and RevE devices meeting his limitation, as discussed in the context of the "second set of LEDs" limitation of '502 patent claim 28. See CIB at 113. In addition, the evidence shows that there is a second set of LEDs in the RevA device with the same wavelengths as the first set, as discussed by Mr. Scruggs. See Tr. (Scruggs) at 405:8-406:3.

d. Element [8C]: "four photodiodes"

Complainants identify four photodiodes in each of the RevA, RevD, and RevE devices, citing the same evidence discussed above in the context of the "photodiodes" limitation of '501 patent claim 1. *See* CIB at 113. Apple disputes whether the evidence is sufficient to show the presence of these photodiodes, *see* RIB at 56, but the evidence shows, by a preponderance, that the RevA, RevD, and RevE devices each contain four photodiodes, for the reasons discussed above in the context of the "photodiodes" limitation of '501 patent claim 1.

e. Element [8D]: "a protrusion comprising a convex surface, at least a portion of the protrusion comprising an opaque material"

There is no dispute that the RevA, RevD, and RevE devices each contain a protrusion comprising a convex surface, which includes a portion with opaque material, as discussed above in the context of the "protrusion" and "openings" limitations of '501 patent claim 1. See CIB at

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113. The evidence shows, by a preponderance, that this limitation is met by the RevA, RevD, and RevE devices.

f. Element [8E]: "a plurality of openings provided through the protrusion and the convex surface, the openings aligned with the photodiodes"

Complainants identify a "plurality of openings" in the RevA, RevD, and RevE devices, citing the same evidence discussed above in the context of the "plurality of openings" limitation of '501 patent claim 1. See CIB at 113. Apple disputes this limitation based on its erroneous construction for the term "openings." See RRB at 46. As discussed above in the context of the "plurality of openings" limitation of '501 patent claim 1, the evidence shows, by a preponderance, that this limitation is met by the RevA, RevD, and RevE devices.

g. Element [8F]: "a separate optically transparent window extending across each of the openings"

There is no dispute that the RevA, RevD, and RevE devices each contain optically transparent windows extending across each of the identified openings, as discussed above in the context of the "plurality of openings" limitation of '501 patent claim 1. *See* CIB at 113-14. The evidence shows, by a preponderance, that this limitation is met by the RevA, RevD, and RevE devices.

h. Element [8G]: "one or more processors configured to receive one or more signals from at least one of the photodiodes and output measurements of a physiological parameter of a user"

There is no dispute that the RevA, RevD, and RevE devices each contain processors that receive signals from the photodiodes, as discussed above in the context of the "processors" limitation of '501 patent claim 1. *See* CIB at 114. Apple disputes whether these processors calculate oxygen saturation, RIB at 56, but as discussed above in the context of the preamble of the '501 patent claim 1, a preponderance of the evidence shows that the RevA, RevD, and RevE

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devices measure and calculate oxygen saturation. The evidence shows, by a preponderance, that this limitation is met by the RevA, RevD, and RevE devices.

i. Element [8H]: "a housing"

There is no dispute that the RevA, RevD, and RevE devices each have a housing. *See* CIB at 114-15. Dr. Madisetti identified photographs of the housing for the RevA, RevD, and RevE devices. Tr. (Madisetti) at 725:19-726:1; CDX-0011C.066 (citing CX-0661C; CX-1058C; CX-1415C; CX-0784C); *see also* CPX-052C; CPX-058C; CPX-019C; CPX-020C; CPX-065C. Mr. Scruggs also testified that the RevA, RevD, and RevE devices each have a housing. Tr. (Scruggs) at 405:8-06:3, 406:23-407:18, 408:20-409:14. The evidence shows, by a preponderance, that this limitation is met by the RevA, RevD, and RevE devices.

j. Element [8I]: "a strap configured to position the housing proximate tissue of the user when the device is worn"

There is no dispute that the RevE devices have straps for a user's wrist. See CIB at 115; CPX-019C, CPX-020C, CPX-065C. In addition, as discussed above in the context of the preamble of '501 patent claim 1, the undersigned finds that the record evidence is sufficient to find that the RevA and RevD devices had straps.

k. Element [12]: "the physiological parameter comprises oxygen or oxygen saturation"

Claim 12 of the '648 patent depends from claim 8 and requires that "the physiological parameter comprises oxygen or oxygen saturation." There is no dispute with respect to this limitation, except to the extent that Apple disputes the satisfaction of the preamble limitation regarding the measurement of a physiological parameter. *See* CIB at 115; RIB at 56. The undersigned finds that the RevA, RevD, and RevE devices are configured to determine

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measurements of blood oxygen for the same reasons discussed above in the context of the preamble and the "physiological parameter" limitation of '501 patent claim 1.

Accordingly, because each limitation of the claim is satisfied, the undersigned finds that the RevA, RevD, and RevE devices practice claim 12 of the '648 patent.

5. '648 Patent Claim 24

a. Element [20 preamble]: "A user-worn device configured to non-invasively determine measurements of a user's tissue, the user-worn device comprising:"

The preamble of '648 patent claim 20 requires "[a] user-worn device configured to non-invasively determine measurements of a user's tissue." The parties' disputes with respect to this preamble are the same as those addressed above in the context of the preamble of '501 patent claim 1. *See* CIB at 115; RIB at 55-56. As discussed above in the context of the preamble of '501 patent claim 1, Complainants have shown by a preponderance of the evidence that the RevA, RevD, and RevE devices are user-worn devices that measure blood oxygen saturation, meeting the limitations of the preamble of '648 patent claim 20.

b. Element [20A]: "a plurality of light emitting diodes (LEDs)"

There is no dispute that the RevA, RevD, and RevE devices each contain LEDs, as discussed above in the context of the "LEDs" limitation of '501 patent claim 1. See CIB at 115.

c. Element [20B]: "at least four photodiodes configured to receive light emitted by the LEDs, the four photodiodes being arranged to capture light at different quadrants of tissue of a user"

With respect to the "four photodiodes" limitation of '648 patent claim 20, Complainants rely on the same evidence discussed above in the context of the "four photodiodes" limitation of '502 patent claim 28 for the RevD and RevE devices. *See* CIB at 115-16. Complainants further

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submit that the RevA has four photodiodes arranged in a quadrant configuration, citing a photograph and technical drawings. See CX-0661C (photo); CX-0473C (schematic) at 1, 3; CX-1111C (CAD). Apple argues that Complainants' evidence with respect to this limitation is unreliable, see CIB at 56, but for the same reasons discussed above in the context of the "at least three photodiodes" limitation of '501 patent claim 1, Complainants have shown by a preponderance of the evidence that the RevA, RevD, and RevE devices each have four photodiodes arranged in a quadrant configuration that meet this claim limitation.

d. Element [20C]: "a protrusion comprising a convex surface"

There is no dispute that the RevA, RevD, and RevE devices each contain a protrusion comprising a convex surface, which includes a portion with opaque material, as discussed above in the context of the "protrusion" limitation of '501 patent claim 1. *See* CIB at 116. The evidence shows, by a preponderance, that this limitation is met by the RevA, RevD, and RevE devices.

e. Element [20D]: "a plurality of through holes, each through hole including a window and arranged over a different one of the at least four photodiodes"

Complainants identify "through holes" in the RevA, RevD, and RevE devices, citing the same evidence discussed above in the context of the "plurality of openings" limitation of '501 patent claim 1. See CIB at 116. Apple disputes this limitation based on its erroneous construction for the term "openings." See RRB at 46. As discussed above in the context of the "plurality of openings" limitation of '501 patent claim 1, the evidence shows, by a preponderance, that this limitation is met by the RevA, RevD, and RevE devices.

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f. Element [20E]: "one or more processors configured to receive one or more signals from at least one of the photodiodes and determine measurements of oxygen saturation of the user"

There is no dispute that the RevA, RevD, and RevE devices each contain processors that receive signals from the photodiodes, as discussed above in the context of the "processors" limitation of '501 patent claim 1. *See* CIB at 116-17. Apple disputes whether these processors calculate oxygen saturation, RIB at 56, but as discussed above in the context of the preamble of the '501 patent claim 1, a preponderance of the evidence shows that the RevA, RevD, and RevE devices measure and calculate oxygen saturation. The evidence shows, by a preponderance, that this limitation is met by the RevA, RevD, and RevE devices.

g. Element [24]: "wherein the protrusion comprises opaque material configured to substantially prevent light piping"

Claim 24 of the '648 patent depends from claim 20, further requiring that "the protrusion comprises opaque material configured to substantially prevent light piping." There is no dispute that the identified protrusion in the RevA, RevD, and RevE devices meets this limitation, as discussed above in the context of the "opaque lateral surface" limitation of '501 patent claim 1.

See CIB at 117.

Accordingly, because each of the limitations of claims 20 and 24 are satisfied, the undersigned finds that the RevA, RevD, and RevE devices practice claim 24 of the '648 patent.

6. '648 Patent Claim 30

Claim 30 of the '648 patent depends from claim 20, further requiring that "the protrusion further comprises one or more chamfered edges." There is no dispute that the identified protrusions in the RevA, RevD, and RevE devices have chamfered edges. *See* CIB at 117.

Dr. Madisetti identified chamfered edges on engineering drawings for the RevA, RevD, and

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RevE. Tr. (Madisetti) at 726:2-14; CDX-0011C.067 (citing CX-1111C (RevA); CX-1124C (RevD); CX-1125C (RevE)).

Accordingly, because each of the limitations of claims 20 and 30 are satisfied, the undersigned finds that the RevA, RevD, and RevE devices practice claim 30 of the '648 patent.

7. Domestic Industry Existing at the Time of the Complaint

Apple argues that no patent-practicing domestic industry article existed at the time of the complaint. RIB at 42-45; RRB at 12-14. Complainants dispute Apple's contentions. CRB at 30-32. As discussed above, Complainants have shown by a preponderance of the evidence that the RevA, RevD, and RevE devices practice claim 12 of the '501 patent and claims 12, 24, and 30 of the '648 patent, and that the RevD and RevE devices also practice claim 28 of the '502 patent.

With respect to a domestic industry that is alleged to exist at the time of the complaint, the Commission has held that a domestic industry article must exist at that time. See Thermoplastic-Encapsulated Electric Motors, Comm'n Op. at 9, EDIS Doc. ID 684974 ("Both Federal Circuit law and Commission precedent require the existence of actual 'articles protected by the patent' in order to find that a domestic industry exists.") (citing Microsoft Corp. v. Int'l Trade Comm'n, 731 F.3d 1354 (Fed. Cir. 2013) ("[a] company seeking section 337 protection must . . . provide evidence that . . . relates to an actual article that practices the patent")); id. at 10 (finding that no domestic industry "exists" relating to the articles protected by the patent where evidence failed to show "the presence of an article protected by the patent at the time of the complaint").

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In consideration of the parties' arguments, the undersigned finds that the RevA, RevD, and RevE devices have been shown to be articles protected by claims of the Poeze patents existing at the time of the complaint. As discussed *supra*, although the RevA and RevD devices were produced in discovery without a strap, a preponderance of the evidence shows that these devices were user-worn devices before the filing of the complaint. *See* Tr. (Scruggs) at 405:8-406:3, 406:23-407:18, 460:13-17; Tr. (Al-Ali) at 260:11-25:14, 265:15-268:21, 270:17-22, 276:12-278:3; CX-0378C at 27.

Apple further argues that the laptop Mr. Scruggs used to display the oxygen saturation measurement from the RevA sensor during discovery was not used with this sensor before the filing of the complaint, RIB at 43-44, but this laptop is not part of the domestic industry article protected by the identified claims of the Poeze patents (Complainants do not assert that the RevA practices claim 22 of the '502 patent, which requires a display). *See* CRB at 30-31.

Mr. Scruggs's laptop was part of the demonstration showing that the RevA sensor was configured as required by the claims, *see* Tr. (Madisetti) at 757:16-23; CX-0836C (demonstration photos) at 4, but the laptop is not part of the domestic industry article—the RevA had the required configuration even in the absence of the laptop.²¹

With respect to the RevD sensor, Apple argues that software was loaded on this device on July 30, 2021, after the complaint was filed. RIB at 42-43; *see* Tr. (Scruggs) at 459:4-460:7; Tr. (Sarrafzadeh) at 1121:9-24; RX-1183C.0035-39. As discussed above, however, Mr. Al-Ali described testing of RevD sensors in early 2021—before the filing of the complaint. Tr. (Al-Ali)

²¹ As described by Mr. Al-Ali, an October 2020 presentation describes internal testing of the oxygen saturation measurements of prototype sensors consistent with the RevA design. Tr. (Al-Ali) at 272:16-277:13; CX-0378C at 32.

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at 276:17-278:13. A preponderance of the evidence thus shows that the RevD existed prior to the complaint.²²

With respect to the RevE devices, Apple argues that the software installed on these devices has a "known date" of July 9, 2021, and this software was loaded on these devices in September and October 2021. *See* RIB at 42-43; Tr. (Scruggs) at 457:12-25, 458:1-459:2, 460:23-461:16; Tr. (Sarrafzadeh) at 1121:9-24; RX-1183C.0035-39. At the hearing, Mr. Scruggs could not specifically identify a date when the RevE devices were made, stating that they were "built between May and September 2021," a range of dates that includes the date the complaint was filed. Tr. (Scruggs) at 398:20-23; *see id.* at 458:1-459:3 (admitting that CPX-0020C was created in September 2021). The evidence shows that at least one of the RevE devices produced (CPX-0019C) existed at the time of the complaint—the evidence shows that software was loaded on this device on July 9, 2021, ²³ which pre-dates the filing date of the amended complaint, July 12, 2021, as recognized in the Commission's Notice of Institution. 86 Fed. Reg. 46275. ²⁴ Moreover, Mr. Al-Ali described testing of RevE devices (though not the

²² Apple's arguments focus on the physical devices produced in discovery, *e.g.*, CPX-0058C, which were loaded with specific software, but the circumstantial evidence regarding testing shows, by a preponderance of the evidence, that prototype devices with designs that are consistent with the asserted domestic industry products were operational before the filing of the complaint and subject to testing. *See* Tr. (Ali-Ali) at 272:16-275:12, 276:12-278:3, 318:15-22; CX-0378C at 32; CX-0494C; n.16 *supra*.

²³ Complainants acknowledge that these devices were altered after the filing of the complaint with "different firmware versions prior to and subsequent to that version for development," but have represented that the July 9 version of the software was restored in October 2021. See RX-1183C.0037-.0039; Tr. (Scruggs) at 457:9-21 (software was installed on physical 19 on July 9, 2021).

²⁴ The original complaint was filed on June 30, 2021, with a redacted public version of an amended complaint filed July 7, 2021, a full confidential version of the amended complaint filed on July 12, 2021, and a supplement to the complaint filed on July 19, 2021. *See* EDIS Doc. ID 745713, 746186, 746514, 747244. *See In re Samsung Electronics Co., Ltd.*, 2 F.4th 1371, 1376 (Fed. Cir. 2021) (amended complaints supersede the original complaint); *Nolen v. Lufkin Indus., Inc.*, 466 Fed. Appx. 895, 898 (Fed. Cir. 2012) ("Generally, an amended pleading supersedes the original for all purposes").

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specific devices produced) in June 2021. Tr. (Al-Ali) at 316:2-317:20 (citing CX-0494C and explaining "that data was collected on June 29th). This record is sufficient to show, by a preponderance of the evidence, that RevE devices existed and practiced asserted claims of Poeze patents at the time the complaint was filed.

* * *

Accordingly, Complainants have shown that the technical prong of the domestic industry requirement is satisfied with respect to a domestic industry existing at the time of the complaint for the Poeze patents.

8. Domestic Industry in the Process of Being Established

Complainants have separately alleged that there is a domestic industry in the process of being established. CIB at 305-09; see Amended Complaint ¶ 86. In Certain Stringed Musical Instruments & Components Thereof ("Stringed Instruments"), the Commission held that a domestic industry is in the process of being established when (1) a complainant takes "the necessary tangible steps to establish such an industry in the United States," and (2) there is a "significant likelihood that the industry requirement will be satisfied in the future." Inv. No. 337-TA-586, Comm'n Op. at 14-17, EDIS Doc. ID 300615 (May 16, 2008). The Commission recently declined to adopt an ID's finding that a currently existing article must exist at the time of the complaint to show a domestic industry in the process of being established. Certain Televisions, Remote Controls, and Components Thereof, Comm'n Op., Inv. No. 337-TA-1263, 2022 WL 17486245, at *15 (Nov. 30, 2022) ("The Commission, however, does not adopt the ID's finding that a currently existing physical article must exist at the time of the complaint filing to show a domestic industry in the process of being established."). The Commission further found that a domestic industry in the process of being established had not been shown because

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the record lacked sufficient evidence of a future physical article that would practice the patent.

See id. (Roku failed to produce "sufficient evidence of how . . . [the] domestic industry device . .

will operate so as to allow the parties to probe in discovery, and the Commission to make a determination, as to whether Gazelle will practice the '875 patent") (emphasis added). The Commission's discussion indicates that a physical article practicing the patent need not yet exist to prove a "process of being established claim."

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Following this guidance, the evidence of record shows, by a preponderance, that the technical prong of the domestic industry requirement is satisfied based on an industry in the process of being established. As discussed *supra*, the evidence shows that the RevA device practices claim 12 of the '501 patent and claims 12, 24, and 30 of the '648 patent. Similarly, the RevD and RevE devices meet all of the limitations of claim 12 of the '501 patent, claim 28 of the '502 patent, and claims 12, 24, and 30 of the '648 patent.

Even if certain of the Masimo Watch prototypes were missing limitations of the Poeze patents, e.g., the "user-worn" limitation in the claim preambles, the evidence shows that at the

²⁵ See also id. ("Respondents have had no opportunity to evaluate . . . whether Roku's future promised product actually would practice the claims of the '875 patent") (quoting ID with approval); id. (finding that Roku failed to meet its burden of showing "that there was a significant likelihood that the Gazelle Remote (or any other physical article) would practice one or more claims of the '875 patent in the future"); id. ("Evidence of a complainant's progress towards an article that will practice one or more claims of the asserted patent as of the complaint filing date is relevant to whether the complainant has taken the necessary tangible steps to establish an industry, and whether there is a significant likelihood that the domestic industry requirement will be satisfied in the future").

²⁶ At the time the parties filed their post-hearing briefs, the Commission had not yet addressed in this manner "the circumstances, if any, in which a complainant can demonstrate a domestic industry in the process of being established absent the existence of a protected article." *Thermoplastic-Encapsulated Motors*, Comm'n Op. at 11-12, 2019 WL 9596564, at *7 (EDIS Doc. ID 684974); *cf. Certain Mobile Devices with Multifunction Emulators*; Inv. No. 337-TA-1170, Initial Determination at 148-52, EDIS Doc. ID 738549 (Mar. 16, 2021) (finding satisfaction of the technical prong in the absence of a physical article based on complainants' "tangible and necessary steps to practice the claim" and a "significant likelihood that the practice will occur."), *reviewed and taking no position on this issue*, Comm'n Notice, EDIS 747056 (July 16, 2021).

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time of the complaint, Masimo had taken necessary "tangible steps" in engineering and research and development towards a product that practiced claims of the Poeze patents. As described above, Masimo's design documents and testing results show that the Masimo Watch prototypes in development meet the limitations of the Poeze patents. The Mr. Scruggs described the development process for Masimo Watch prototypes as an iterative process. See id. at 393:12-20 ("we've designed, built, and tested many iterations of the Masimo Watch"), 402:2-12 (describing "the progression of the different sensor designs"); see also Tr. (Muhsin) at 342:25-343:7 (describing "many iterations of wrist sensors"), 345:2-7 (describing "[m]any iterations on the watch through the design phases"); Tr. (Al-Ali) at 275:13-276:11 (describing ongoing testing of sensor designs, and with each subsequent design, "[i]t gets a little bit better"). Thus, even if the evidence were insufficient to show that the RevA, RevD, and RevE devices existing at the time of the complaint practiced each of the limitations of the asserted claims, the evidence would be sufficient to show a domestic industry in the process of being established.

Accordingly, the undersigned finds that Complainants have satisfied the technical prong with respect to claim 12 of the '501 patent, claim 28 of the '502 patent, and claims 12, 24, and 30 of the '648 patent, for a domestic industry in the process of being established based on the RevA, RevD, and RevE devices.

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²⁷ Apple argues that its experts were not allowed certain access to the prototypes (*see* RIB at 48-49), but Complainants produced schematics, source code, and the data from Masimo's testing regarding these prototypes in discovery, and provided witnesses for deposition. *See* CRB at 29-30, 33-34. Many of Apple's complaints regarding domestic industry discovery were addressed in the context of Apple's motion for sanctions and Apple's motion to strike domestic industry contentions. *See* Order No. 31 (Apr. 8, 2022); Order No. 32 (May 5, 2022). The record shows that Apple was provided a reasonable opportunity to evaluate whether Masimo's development activities would result in a product practicing the asserted claims. *See Certain Televisions, Remote Controls, and Components Thereof,* Inv. No. 337-TA-1263, Comm'n Op., 2022 WL 17486245, at *15 (Nov. 30, 2022) (noting that respondents should be given an "opportunity to evaluate in fact or expert discovery whether [complainant]'s future promised product actually would practice the claims").

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G. Invalidity - Anticipation/Obviousness

Apple alleges that the asserted claims of the Poeze patents are invalid as anticipated in view of U.S. Patent No. 7,620,212 (RX-0411), entitled "Electro-Optical Sensor," which issued from an application filed on August 12, 2003, identifying assignee Lumidigm, Inc. (RX-0411 is referenced herein as "Lumidigm"). RIB at 67-103. There is no dispute that Lumidigm is prior art to the Poeze patents.

Apple further alleges that the asserted claims of the Poeze patents are invalid as obvious in view of Lumidigm alone or in combination with U.S. Patent No. 5,766,131 (RX-0666, "Seiko '131"), which issued from an application filed on July 30, 1996; U.S. Patent No. 4,224,948 (RX-0670, "Cramer"), which issued from an application filed on November 24, 1987, the textbook Design of Pulse Oximeters by J.G. Webster (RX-0035, "Webster"), published in 1997; and/or U.S. Patent No. 9,001,047 (RX-0673, "Apple '047"), which issued from an application filed on January 4, 2008. RIB at 67-103. There is no dispute that these references are prior art to the Poeze patents.

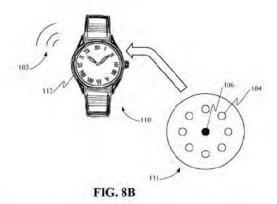
The undersigned finds that Lumidigm does not anticipate any asserted claim of the Poeze patents at least because, as discussed below, it does not include the required "protrusion" with a "convex" surface as set forth in all asserted claims. Accordingly, the relevant analysis for all asserted claims is an obviousness assessment. For the reasons discussed below, the evidence shows, clearly and convincingly, that '501 patent claim 12 is invalid as obvious. Apple has not shown, clearly and convincingly, that any of the asserted claims of the '502 patent or the '648 patent is invalid as obvious.

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1. '501 Patent Claim 12

a. Element [1 preamble]: "A user-worn device configured to noninvasively measure a physiological parameter of a user, the user-worn device comprising:"

Apple submits that Lumidigm discloses a "user-worn device configured to noninvasively measure a physiological parameter of a user" in Figure 8B, a "biometric reader" that "is built into the case of a wristwatch." RX-0411 at 11:60-12:2; see Tr. (Warren) at 1207:23-1208:13; RDX-8C.23.



This device "operates based upon signals detected from the skin in the area of the wrist." RX-0411 at 11:60-63. Apple submits that Lumidigm discloses embodiments in which the sensor is incorporated into a user-worn wristwatch, and that in certain embodiments, Lumidigm's sensor uses those signals to "measure physiological parameters, based on the 'concentration of a substance in the individual's tissue,' including 'oxygenation and/or hemoglobin levels in the blood." RIB at 70 (citing RX-0411 at 19: 16-28, 11:61-64, Tr. (Warren) at 1208:1-13, 1214:12-1215:4); see also RIB at 68.

Complainants argue that Lumidigm fails to disclose non-invasively measuring a physiological parameter in the wristwatch embodiment of Figure 8B. CIB at 124-26.

Complainants submit that the "biometric reader" of Lumidigm is used to identify a user based on "tissue spectral data" and not to measure a physiological parameter. *Id.* (citing RX-0411 at

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10:42-59, 5:30-44, 11:15-28, 11:60-61); see Tr. (Madisetti) at 1340:17-25, 1341:8-12. Complainants argue that the "extended functionality" of Lumidigm is not disclosed in connection with the wristwatch embodiment. See Tr. (Madisetti) at 1330:6-8, 1330:20-1331:11, 1340:17-1341:14. Complainants describe these functionalities as part of a "brainstorming session," relying on the testimony of Robert Rowe, one of the named inventors of Lumidigm. See Tr. (Rowe) at 1146:18-1147:3.

In consideration of the parties' arguments, the undersigned finds that Lumidigm meets the limitations of the preamble of '501 patent claim 1 by disclosing a user-worn wristwatch embodiment with a biometric sensor configured to measure a physiological parameter. See RX-0411 at 3:35-47, 11:60-12:2, 19:18-28; Tr. (Warren) at 1208:1-12; RDX-8.20 (identifying, inter alia, incorporation of a "alcohol-monitor function" and a "bilirubin-monitor function"). Lumidigm describes the measurement of such parameters as a non-invasive "spectroscopic function." Id. at 3:45-47, 19:18-28. The undersigned agrees with Complainants that the primary focus of Lumidigm is a biometric sensor for identification, but Lumidigm clearly discloses additional "extended functionality" using "the spectral-analysis capabilities of the biometric sensor," including where "the spectral analysis is used to identify a physiological state of an individual." Id. at 18:26-28. Lumidigm provides that "identification of such a physiological state may be made by measuring the spectral variation of a measured spectrum for light scattered by the tissue of the individual, and comparing it with a reference spectral variation." Id. at 18:29-32. Lumidigm describes, inter alia, examples of a bilirubin monitor and a blood-alcohol monitor. Id. at 19:29-50.

These disclosures of physiological monitoring are in the "extended functionality" section of the Lumidigm specification, which are clearly applicable to the user-worn wristwatch

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embodiment, with the specification stating that the extended functionalities are "especially suitable when the biometric sensor is comprised by a portable device, such as a portable electronic device." *Id.* at 17:67-18:2. The specification explicitly identifies "a watch" as an example of a "portable electronic device having extended functionality." *Id.* at 3:21-37. These extended functionalities, in combination with biometric functions, are also reflected in the claims of the Lumidigm patent, which claim a device "further configured to operate the biometric sensor to perform a nonbiometric function," and providing a limited set of nonbiometric functions including "an alcohol-monitor function, a bilirubin-monitor function," and "a hemoglobin-monitor function." *Id.* at 25:35-45 (claims 11 and 12).

Complainants cite evidence that the Lumidigm inventors never developed a device with the described extended functionalities, *see* CIB at 126-27, but "the invention in a prior art publication need not have actually been made or performed to satisfy enablement." *In re Antor Media Corp.*, 689 F.3d 1282, 1290 (Fed. Cir. 2012). Moreover, there is a "presumption . . . that both the claimed and unclaimed disclosures in a prior art patent are enabled." *Amgen Inc. v. Hoechst Marison Roussel, Inc.*, 314 F.3d 1313, 1355 (Fed. Cir. 2003). ²⁸

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while this statement in *Amgen* arose in the context of an anticipation analysis, it is relevant to obviousness as well. While a non-enabled prior art reference can be used in an obviousness analysis for what it teaches, "the evidence of record must still establish that a skilled artisan could have made the claimed invention." *Raytheon Techs. Corp. v. GE Co.*, 993 F.3d 1374, 1381 (Fed. Cir. 2021) ("even though a non-enabling reference can play a role in an obviousness analysis, the evidence of record must still establish that a skilled artisan could have made the claimed invention"). The Federal Circuit has held that "[i]n the absence of . . . other supporting evidence to enable a skilled artisan to make the claimed invention, a standard applied to anticipatory references." *Id.* at 1381. This holding indicates that the same presumption applied to asserted anticipation references can be applied to an embodiment disclosed in a prior art obviousness reference. *See also In re Kumar*, 418 F.3d 1361, 1368 (Fed. Cir. 2005) ("when a *prima facie* case of obviousness is deemed made . . . rebuttal may take the form of evidence that the prior art does not enable the claimed subject matter . . . [t]he applicant has the burden of coming forward with evidence in rebuttal").

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Complainants identify evidence that measuring blood oxygen at the wrist would have been unlikely to be successful at the time of the Poeze patents, *see* CIB at 127-29, but claim 1 of the '501 patent is not limited to blood oxygen—the preamble limitations can be met by a device that measures any "physiological parameter." Lumidigm describes functionality for measuring several different physiological parameters, *e.g.*, hemoglobin levels, bilirubin, and blood alcohol, and Complainants have not offered any evidence to rebut the presumption that these functionalities are enabled by Lumidigm's disclosure. ²⁹ Accordingly, the undersigned finds that Lumidigm clearly and convincingly discloses the preamble limitation of claim 1.

b. Element [1A]: "at least three light emitting diodes (LEDs)"

There is no dispute that Lumidigm discloses at least three LEDs. See CIB at 71-72. Lumidigm describes a "sensor assembly" that "comprises a plurality of light sources." RX-0411 at 6:22-24. Lumidigm explicitly states that these light sources "may comprise light emitting diodes ('LEDs')." Id. at 6:38-43. There are more than three light sources depicted in the wristwatch embodiment in Figure 8B, and Lumidigm provides that "FIG. 8B again shows the equidistant-sensor geometry of FIG. 4 for illustrative purposes only; more generally, any of the sensor geometries previously disclosed or other equivalent configurations can be used for this application." Id. at 11:65-12:2. One such alternative to the sensor geometry of Figure 4 is depicted in Figure 6, which shows 3 light sources:

²⁹ Complainants' arguments regarding blood oxygen are discussed *infra* in relation to the '502 and '648 patents. As set forth therein, the undersigned agrees with Complainants that there is no prior art enablement of a wristwatch that measures blood oxygen.

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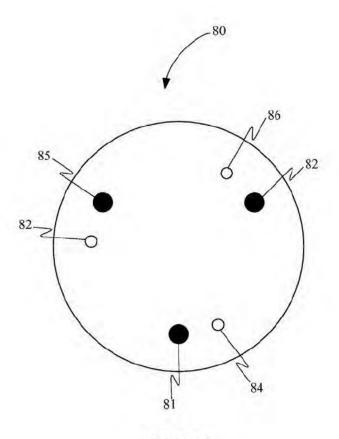


FIG. 6

Id. at Fig. 6, 9:12-25 (identifying "light sources 82, 84, 86"). Moreover, Lumidigm explicitly discloses that "any of the sensor geometries previously disclosed or other equivalent configurations can be used for" the wristwatch embodiment. Id. at 11:65-12:2. Given this explicit statement, the evidence indicates that Lumidigm discloses the wristwatch embodiment using the sensor geometry of Figure 6.

c. Element [1B]: "at least three photodiodes arranged on an interior surface of the user-worn device and configured to receive light attenuated by tissue of the user"

Apple contends that Lumidigm discloses "at least three photodiodes." RIB at 72-74; see Tr. (Warren) at 1208:25-1209:17. Apple cites to Figure 6 of Lumidigm, depicted above, which shows "three detectors 81, 83, 85." RX-0411 at 9:15-18. Lumidigm also discloses that "[t]he detector type and material is chosen to be appropriate to the source wavelengths and the

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measurement signal and timing requirements," providing examples of "PbS, PbSe, InSb, InGaAs, . . . ," and for a "spectral range from about 350 nm to about 1100 nm, a suitable detector material is silicon." *Id.* at 6:56-63. Dr. Warren testified at the hearing that a detector made of indium gallium arsenide (InGaAs) or silicon would be a photodiode. Tr. (Warren) at 1209:14-17. This testimony is corroborated by references to silicon photodiodes in other prior art references. *See* RX-0035.0053 ("The photodetector is a silicon photodiode"); RX-1221 ("silicon NPN planar epitaxial phototransistors").

Apple further contends that the photodiodes disclosed in Lumidigm are "arranged on an interior surface," citing Figure 2, which depicts "the detector 36 recessed from the sensor surface 39 in optically opaque material 37 that makes up the body of the sensor head 32." RX-0411 at 8:1-4.

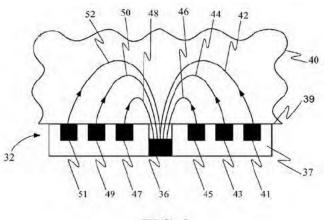


FIG. 2

Id. at Fig. 2; RIB at 73-74. Lumidigm describes this "optical geometry" as a "diffuse reflectance sampling geometry where the light sources and detector lie on the same side of the tissue." RX-0411 at 7:12-14. While one detector is depicted in Figure 2, Apple cites Lumidigm's disclosure that "[t]he detector 36 may comprise a single element, a plurality of discrete elements, or a one-or two-dimensional array of elements." Id. at 4:54-56.

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Complainants argue that there is no explicit disclosure of photodiodes in Lumidigm and there is no disclosure of three photodiodes arranged on an interior surface in connection with the wristwatch embodiment. CIB at 130; CRB at 46.

In consideration of the parties' arguments, the undersigned finds that Lumidigm meets the "at least three photodiodes" limitation of '501 patent claim 1. Lumidigm clearly discloses silicon detectors, and Complainants fail to offer any rebuttal to Mr. Warren's testimony, corroborated by other prior art disclosures, that the silicon detectors are photodiodes. *See* Tr. (Warren) at 1209:14-17. Three photodiodes are explicitly disclosed in Figure 6 of Lumidigm. *See* RX-0411 at 9:15-25. As discussed above, Lumidigm contains an express disclosure that "any of the sensor geometries previously disclosed or other equivalent configurations can be used for" the wristwatch embodiment. *Id.* at 11:65-12:2.

Although there is no explicit depiction of three detectors arranged on an interior surface like the single detector in the cross-section of Figure 2, the Federal Circuit has held that "a reference can anticipate a claim even if it 'd[oes] not expressly spell out' all the limitations arranged or combined as in the claim, if a person of skill in the art, reading the reference, would 'at once envisage' the claimed arrangement or combination." *Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381 (Fed. Cir. 2015). Relying on this precedent, the Federal Circuit upheld a finding of anticipation based on prior art that "explicitly contemplates the combination of the disclosed functionalities." *Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1343 (Fed. Cir. 2016). Lumidigm's Figure 2 is a cross-sectional view of the arrangement of light sources and detector depicted in Figure 3, *id.* at 8:33-42, and the arrangement of three light sources and three detectors in Figure 6 is one specifically disclosed alternative to Figure 3. *See id.* at 9:12-25; Tr. (Warren) at 1211:15-20 (cross-section for Fig. 6 would be similar to Fig.

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2).³⁰ As recognized by Dr. Warren, Lumidigm expressly discloses the use of these source-detector arrangements in the wristwatch embodiment. *See* Tr. (Warren) at 1214:12-1215:4; RX-0411 at 11:65-12:2.³¹ Accordingly, the undersigned finds that Lumidigm's disclosures meet this limitation in the context of Lumidign's wristwatch embodiment.

d. Element [1C]: "a protrusion arranged over the interior surface, the protrusion comprising a convex surface"

Apple contends that Lumidigm discloses a protrusion meeting the limitations of '501 patent claim 1. RIB at 74-75. Apple points to sensor head 32 depicted in Figure 2 of Lumidigm, citing a statement in the specification that "[t]he sensor head 32 may also have a compound curvature on the optical surface to match the profile of a device in which it is mounted, to incorporate ergonomic features that allow for good optical and mechanical coupling with the tissue being measured, or for other technical or stylistic reasons." RX-0411 at 7:57-63. Apple relies on Dr. Warren's testimony that a person of ordinary skill in the art would read the disclosure of a "compound curvature" and "realize that a practical implementation of this would be a convex surface." Tr. (Warren) at 1211:2-8.

Complainants argue that Lumidigm's sensor head 32 is flat, and there is no explicit disclosure of a protrusion comprising a convex surface. RIB at 130-32. Dr. Madisetti testified that Lumidigm's description of curvature to match the profile of a wristwatch would likely result in a concave shape, citing the deposition testimony of Robert Rowe, one of the Lumidigm

³⁰ Figures 3, 4, and 6 all depict source-detector arrangements in a circular shape that appears the same as the back of the wristwatch depicted in Figure 8B. *See* RX-0411 at Fig. 3, Fig. 4, Fig. 6, Fig. 8B.

³¹ In addition, the evidence shows that Figure 2 depicts sensor surface 39 above an "interior surface" where detector 36 is located. *See* RX-0411 at 8:1-4 ("FIG. 2 illustrates a sensor-head geometry wherein the detector 36 is recessed from the sensor surface 39 in optically opaque material 37 that makes up the body of the sensor head 32."); Tr. (Warren) at 1209:19-1210:11; RIB at 73-74.

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inventors. Tr. (Madisetti) at 1331:12-1332:24 (citing CX-0279C (Rowe Dep. Tr.) at 69:8-21). Complainants further argue that the statement regarding Lumidigm's wristwatch embodiment describing different configurations of "sensor geometries" only refers to the arrangement of light sources and detectors—not to the shape of the surface of the sensor head. CIB at 132.

In consideration of the parties' arguments, the undersigned finds that the evidence fails to show, clearly and convincingly, that Lumidigm alone discloses the claimed "protrusion comprising a convex surface" limitation of '501 patent claim 1. As depicted in Figure 2 of Lumidigm, sensor surface 39 of sensor head 32 is flat. While the description of "compound curvature" in Lumidigm's specification allows for the possibility of a convex shape, this is insufficient to show that this limitation is inherent in Lumidigm. *See Guangdong Alison Hi-Tech Co. v. Int'l Trade Comm'n*, 936 F.3d 1353, 1364 (Fed. Cir. 2019) ("An element may be inherently disclosed only if it is necessarily present, not merely probably or possibly present, in the prior art." (internal quotations removed)). Apple has not shown, clearly and convincingly, that a convex protrusion is either explicitly or inherently disclosed in Lumidigm.

Apple further contends that modifying Lumidigm to include the claimed protrusion would be obvious because a protrusion with a convex surface was a "well-known idea" in the prior art. RIB at 104-107. Dr. Warren testified that "it was already well-known that a convex curvature itself could be a useful element in increasing signal quality." Tr. (Warren) at 1211:2-8. He further identified convex protrusions in prior art references Seiko 131 and Cramer. *Id.* at 1230:18-1233:14; RDX-8C.67. Seiko 131 provides that "[w]hen the outside surface of the light transmittance plate is a convex surface, pressure is applied to the light transmittance plate by simply holding the outside surface of the light transmittance plate lightly against the body

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surface, and positive contact between the body surface and outside surface of the light transmittance plate can therefore be improved." RX-0666 at 3:22-28.

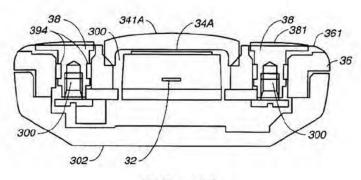


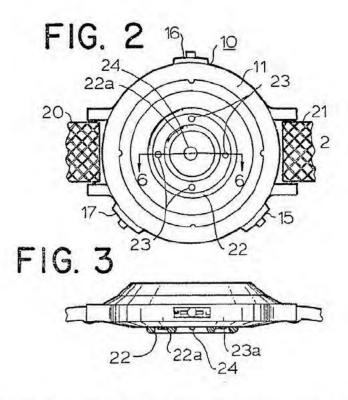
FIG._28

Id. at Fig. 28, 19:5-8 ("outside surface 341A of light transmittance plate 34A may also be convex as shown in FIG. 28."). Dr. Warren testified that "the purpose of this convex surface, as stated in Seiko, is to move residual blood out of the way and increase the quality of the measurement."

Tr. (Warren) at 1231:4-8; RDX-8.67.

Cramer discloses raised portions identified as "boss 22" and "boss 22A," wherein "boss 22 serves to isolate the infra-red detector from ambient light" and "boss 22A prevents direct transmission of light between source 24 and detectors 23." RX-0670 at 5:45-51.

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Id. at Fig. 2, Fig. 3. Cramer further states that "[t]he coaxial arrangement of these three elements provides a relatively large contact surface area resulting in not only effective sensing of a pulse rate but minimum discomfort to the wearer." Id. at 5:48-51. Cramer also states that "[t]he circular array of the detector 23 allows the detection of pulses in a substantial arteriolar-capillary bed within the hemispherical region denoted in Fig. 6 for increased signal to noise ratio and energy utilization." Id. at 5:51-56. Another prior art reference, U.S. Patent No. 4,880,304 (RX-0665, "Nippon"), describes an embodiment where "the portion of the sensor face containing the LEDs and the optical detector protrudes into the tissue slightly, thereby increasing the signal strength of the detected signal." RX-0665 at 5:12-17, Fig. 3b; Tr. (Warren) at 1245:8-16 (Nippon . . . conveys the idea that, if the detector protrudes slightly into tissue, not only can you get more repeatable coupling, but you can increase the sensitivity of the sensor").

Complainants argue that the claimed protrusion is not obvious in view of Lumidigm.

CIB at 130-36. Dr. Madisetti testified that Lumidigm's description of curvature to match the

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profile of a wristwatch would likely result in a concave shape, citing the deposition testimony of Robert Rowe, one of the Lumidigm inventors. Tr. (Madisetti) at 1331:12-1332:24 (citing CX-0279C (Rowe Dep. Tr.) at 69:8-21). Complainants argue that the reference to curvature on Lumidigm's "optical surface" is not the same as Lumidigm's "sensor surface 39." CIB at 131. Complainants further argue that the statement regarding Lumidigm's wristwatch embodiment describing different configurations of "sensor geometries" only refers to the arrangement of light sources and detectors—not to the shape of the surface of the sensor head. *Id.* at 132; see Tr. (Rowe) at 1152:7-21 (referring to the "sensor geometries previously disclosed as Figs. 3 through 7," without referencing Figure 2). Complainants argue that there is no motivation to modify Lumidigm to have a convex surface, because such a shape would not match the profile of a user's wrist and would add to the form factor of a wristwatch. RIB at 133-34; Tr. (Madisetti) at 1331:20-25. In addition, Dr. Madisetti identified a prior art reference expressing skepticism of pulse oximetry when there are "[v]ariations in contact pressure between the sensor and the skin," which would be caused by a convex protrusion. Tr. (Madisetti) at 1338:6-13; CDX-0012C.013 (citing CX-1733 at 2:47-57). Joe Kiani testified that Cercacor engineers had preferred concave surfaces for noninvasive sensors before conducting experiments showing that a convex protrusion produced a better signal. Tr. (Kiani) at 98:9-99:16.

With respect to Cramer, Complainants submit that the convex protrusions are annular rings that are not compatible with the other limitations of the Poeze patents (including Element 1[D] of the '501 patent), such as "openings" or "holes" through the protrusion. CIB at 144-46; CRB at 59. With respect to Seiko 131, Complainants submit that the identified convex protrusion is merely a single transparent window without "openings" or "holes" or "opaque lateral surfaces" (as required by Element [1E] of the '501 patent). CIB at 148-49 (identifying

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"transparent window" in Seiko 131). Complainants further note that Seiko 131 describes a sensor worn on a user's finger, not on the wrist. CRB at 59. Complainants argue that Apple has failed to identify any reason or motivation to modify Lumidigm's wristwatch to incorporate a convex protrusion as disclosed in Cramer or Seiko 131. CIB at 133-34, 151-52; CRB at 60. Complainants further argue that Apple has failed to show that any such combination would have a reasonable expectation of success. CIB at 135, 152-53.

In reply, Apple argues that the "optical surface" described by Lumidigm is the same as the "sensor surface 39" depicted in Figure 2. RRB at 53. Apple further identifies Lumidigm's disclosure of an optical relay "between the sensor surface 39 and the skin 40," wherein "[t]he surface of the light relay can be contoured to fit specific product applications and ergonomic requirements." RX-0411 at 8:19-28. Apple disputes Complainants' interpretation of Mr. Rowe's testimony. RRB at 53-54. Apple further argues that Lumidigm expressly discloses the use of other "geometries" with its wristwatch embodiment. Id. Apple submits that there is no evidence that the prior art "taught away" from convex protrusions and cites prior art references recognizing the benefits of convex surfaces applying pressure to a user's skin. Id. at 55. Apple argues that both Cramer and Seiko 131 disclose convex protrusions and a person of ordinary skill would have been motivated to combine these structures with Lumidigm with a reasonable expectation of success. Id. at 60-62.

In consideration of the parties' arguments, the undersigned finds that Lumidigm's disclosure that the optical surface of its sensor head "may also have a compound curvature," together with prior art knowledge, would have provided one of ordinary skill in the art reason to implement the optical surface in a convex shape for the reasons that are explicitly disclosed in Lumidigm: "to match the profile of a device in which it is mounted, to incorporate ergonomic

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features that allow for good optical and mechanical coupling with the tissue being measured, or for other technical or stylistic reasons." RX-0411 at 7:57-63. In particular, Dr. Warren offers credible testimony that one of ordinary skill in the art would have recognized the benefits of a convex surface at the time of the Poeze patents in terms of signal quality, which is consistent with the disclosures in several prior art references. *See* Tr. (Warren) at 1244:11-1246:3. Seiko 131 identifies a convex surface that improves "positive contact between the body surface and outside surface of the light transmittance plate." RX-0666 at 3:22-28, Fig. 28.³² Prior art reference Nippon similarly describes increased signal strength from a protrusion into the tissue. *See* RX-0665 at 5:12-17, Fig. 3b; RIB 117, 146; Tr. (Warren) at 1245:8-16. These prior art disclosures show, clearly and convincingly, that one of ordinary skill in the art would have had "technical or stylistic reasons" for implementing a convex curvature for Lumidigm's sensor surface. *See* Tr. (Warren) at 1233:1-14; RX-0411 at 7:57-63.³³

The evidence of "teaching away" offered by Complainants is not supported by the record evidence. Dr. Madisetti cites a prior art reference that raises concerns about "[v]ariations in contact pressure between the sensor and the skin," but this reference does not discuss convex surfaces. See CX-1733 at 2:47-57. Mr. Kiani's testimony that concave surfaces were preferred before the invention of the Poeze patents is not corroborated by any evidence from the relevant

³² Lumidigm also discloses a "force sensing functionality . . . to ensure firm contact between the sensor and the skin," RX-0411 at 8:11-14, which addresses a stated goal of Seiko 131 to achieve "sufficient pressure against light transmittance plate 34A." RX-0666 at 19:8-13.

³³ The undersigned agrees with Apple that the "optical surface" and "sensor surface 39" refer to the same surface in the context of Lumidigm's Figure 2. *See* RRB at 53-54. In addition, Figure 2 depicts sensor surface 39 above an "interior surface" where detector 36 is located. *See* RX-0411 at 8:1-4 ("FIG. 2 illustrates a sensor-head geometry wherein the detector 36 is recessed from the sensor surface 39 in optically opaque material 37 that makes up the body of the sensor head 32.").

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timeframe.³⁴ Even if a concave shape would be more likely to conform to the shape of a user's wrist, as argued by Complainants, this does not establish that one of ordinary skill in the art would have avoided a convex shape. As discussed above, several prior art references describe technical benefits associated with a convex protrusion for sensors on the skin.³⁵

The undersigned also finds that one of ordinary skill in the art would have been able to implement a convex optical surface in Lumidigm's wristwatch with a reasonable expectation of success. *See* Tr. (Warren) at 1238:1-6. Lumidigm explicitly discloses that its sensor head could have a "compound curvature on the optical surface." *See* RX-0411 at 7:57-63.³⁶

. See CIB at 134; RRB at 55. In any case, this issue would not preclude a reason to modify Lumidigm in the manner described above. See Allied Erecting and Dismantling Co., Inc., v. Genesis Attachments, LLC, 825 F.3d 1373, 1381 (Fed. Cir. 2016) ("a given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate motivation to combine") (internal quotation omitted).

³⁴ Complainants cite evidence from Apple's several years after the priority date for the Poeze patents. This evidence is addressed *infra* in the context of objective indicia of non-obviousness.

³⁵ There is no evidence that the "form factor" of a convex protrusion would have been relevant to persons of ordinary skill in the art at the time of the Poeze patents—the only evidence that Complainants cite is Dr. Madisetti's conclusory testimony and a statement from Apple's prehearing brief related to the development of the Apple Watch,

³⁶ It is unclear whether Apple argues for a specific physical combination of Lumidigm and Cramer, e.g., by applying Cramer's structure of annular rings and photodiodes to the Lumidigm wristwatch. See RIB at 103-113. However, to the extent this combination is proposed, Apple does not explain how this combination would fit with the multiple LED/multiple photodiode arrangement relied upon for claim elements [1A] and [1B], particularly because Cramer's raised annular rings are designed to separate Cramer's single LED from Cramer's set of equidistant four photodiodes. See RX-0679 at 5:46-48 ("The boss 22A prevents direct transmission of light between source 24 and detectors 23."). In contrast, claim 1 requires at least three LEDs. Similar issues exist for the "protrusion" elements of the '502 and '648 patents, which also require multiple LEDs and photodiodes. See CIB at 143 (claim must be considered as a whole). Moreover, the evidence does not clearly and convincingly show that Cramer discloses a protrusion with openings or through holes within it over photodiodes (as required for Elements [1D], [19C], [28F], [8E], [20C-D]). See CIB at 144-146. Dr. Warren states that Cramer "describes what it calls a raised boss area, which is essentially a convex protrusion" that "consists of two concentric raised annular areas of opaque material." Tr. (Warren) at 1231:18-22. Dr. Madisetti similarly testified that the alleged protrusion is "just two rings." Tr. (Madisetti) at 1334:23-1335:2. The evidence does not clearly and convincingly show that the two raised rings of Cramer would be considered a single "protrusion."

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Based on the above, the evidence shows clearly and convincingly that Lumidigm's disclosure of an optical surface that can have "compound curvature" would have provided a reason for one of ordinary skill in the art to modify the optical surface of Lumidigm's wristwatch embodiment to form a "protrusion comprising a convex surface," and this modification would have had a reasonable expectation of success.

> Element [1D]: "a plurality of openings extending through the e. protrusion and positioned over the three photodiodes"

With respect to the "plurality of openings" limitation, Apple cites to Lumidigm Figure 2, which depicts "the detector 36 recessed from the sensor surface 39 in optically opaque material 37 that makes up the body of the sensor head 32." RX-0411 at 8:1-4. While one detector is depicted in Figure 2, Apple cites Lumidigm's disclosure that "[t]he detector 36 may comprise a single element, a plurality of discrete elements, or a one- or two-dimensional array of elements." Id. at 4:54-56. Apple submits that Lumidigm thus discloses openings positioned over one photodiode or multiple photodiodes. RIB at 75-76.

Apple further contends that the use of openings and holes for photodiodes was well known in the art and disclosed in Cramer and Seiko 131. RIB at 107-110. Dr. Warren testified that openings over photodiodes were well-known at the time of the Poeze patents, recognizing that "[a] detector can't detect light without some sort of opening above it." Tr. (Warren) at 1192:25-1193:6. He identified U.S. Patent No. 3,769,974 (RX-0473, "Smart") as a prior art reference with an example of an opening for a photodiode. *Id.* at 1193:7-18; RDX-8C.10; see RX-0473 at Fig. 1, 3:17-19 ("An annular inner wall 59 is formed of opaque epoxy and blocks the direct transmission of light from the diodes 16 to the phototransistor sensor 28."). In Seiko 131, Apple identifies an opening between the detector and the user's tissue. RIB at 108 (citing RX-0666 at Fig. 28). With respect to Cramer, Apple cites a datasheet for a detector identified in

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Cramer—the CLT 2160 detector, which was described by Dr. Warren as a "can detector" that includes an opening between the photodiode and the surface of the detector. Tr. (Warren) at 1231:23-1232:9, 1234:3-8; see RX-0670 at 5:33-35 ("A suitable detector is the type CLT 2160 photo diode produced by Clairex Electronics, Inc."); RX-1221 (CLT 2160 datasheet).

Complainants dispute Lumidigm's disclosure of this limitation, arguing that there is no protrusion meeting the limitations of the claim and because three photodiodes are not explicitly disclosed in the configuration of Figure 2 or in connection with the wristwatch embodiment. CIB at 138.

With respect to Seiko 131, Complainants argue that there is only one photodiode and one opening, which does not extend through the light transmittance plate identified as the claimed convex surface. CIB at 148-49; CRB at 60-61. With respect to Cramer, Complainants argue that the openings over the photodiodes are between the "boss 22" and "boss 22A" that are identified as convex protrusions and thus do not extend through these protrusions. CIB at 145-46. Complainants further argue that the CLT 2160 datasheet is undated and was not authenticated by any witness. CRB at 63-64.

In consideration of the parties' arguments, the evidence clearly and convincingly shows that Lumidigm meets the "plurality of openings . . . positioned over the three photodiodes" limitation of '501 patent claim 1. As discussed above, the undersigned agrees with Complainants that there is no convex protrusion in Lumidigm, but Lumidigm discloses an opening extending through a protrusion that is positioned over a detector in Figure 2, and as discussed above in the context of the "at least three photodiodes" limitation, Lumidigm clearly shows that the placement of the detector in Figure 2 corresponds to the source-detector arrangement of Figure 3, and that the arrangement of three sources and three detectors in Figure

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6 is a disclosed alternative to Figure 3 for use in the wristwatch embodiment. *See* RX-0411 at 7:5-9:25, 11:65-12:2, Fig. 2, Fig. 3, Fig. 4, Fig. 6, Fig. 8B. Under this arrangement, there is an opening positioned over each photodiode. *See* Tr. (Warren) at 1211:15-20 (cross-section in Fig. 6 would be similar to Fig. 2, with each photodiode recessed an opening over each photodiode). Dr. Warren's testimony and the disclosures in prior art references such as Smart also confirm that such openings over photodiodes were known in the art at the time of the Poeze patents. *See* Tr. (Warren) at 1192:25-1193:18; RX-0473 at 3:17-19, Fig. 1.

Further, as discussed in Part IV.E.1.d *supra*, a person of skill in the art would have reason to implement to modify the optical surface 39 of Lumidigm to form a "protrusion comprising a convex surface." This modified optical surface of the sensor head, like the optical surface of Lumidigm shown in Fig. 2, would extend over the photodiodes and the openings over them. *See* Tr. (Warren) at 1210:13-1211:14; *id.* at 1212:4-10 (sensor head would have same number of openings as photodiodes); RIB at 75. Accordingly, the evidence clearly and convincingly shows that this limitation of '501 patent claim 1 is met by Lumidigm's disclosures.

f. Element [1E]: "the openings each comprising an opaque lateral surface, the plurality of openings configured to allow light to reach the photodiodes, the opaque lateral surface configured to avoid light piping through the protrusion"

With respect to the "opaque lateral surface" limitation, Apple again cites to Lumidigm Figure 2, which depicts "the detector 36 recessed from the sensor surface 39 in optically opaque material 37 that makes up the body of the sensor head 32." RX-0411 at 8:1-4. Lumidigm further provides that "[t]he recessed placement of detector 36 minimizes the amount of light that can be detected after reflecting off the first (epidermal) surface of the tissue." *Id.* at 8:4-7. Lumidigm notes that "reflections from the top surface of tissue (known as 'specular' or 'shunted' light) are

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detrimental to most optical measurements." *Id.* at 7:66-8:1. The effect of the recessed placement of the detector is described as an "optical blocking effect." *Id.* at 8:7-10.

Complainants argue that Lumidigm's disclosure of "optical blocking" is directed to light that is reflected off the surface of the tissue, which is distinct from "light piping." CIB at 139-40; see Tr. (Madisetti) at 1340:8-10. Complainants cite the specification of the Poeze patents, which describes "light piping (e.g., light that bypasses measurement site 102)." JX-001 at 22:48-50. At the hearing, Mr. Kiani described light piping as "light that goes from the LED directly to the photodetector, without going through the tissue." Tr. (Kiani) at 100:14-24.

The evidence clearly and convincingly shows that Lumidigm meets the "opaque lateral surface" limitation of '501 patent claim 1. There is no dispute that Lumidigm discloses an opaque lateral surface in the opening for a detector in Figure 2. Complainants argue that Lumidigm fails to explicitly recognize that this surface is "configured to avoid light piping," but Dr. Warren testified at the hearing that the "shunted" light described in Lumidigm "is what is called light piping in this matter." Tr. (Warren) at 1212:22-1213:3. The undersigned finds Dr. Warren's testimony on this issue to be credible and convincing, and Lumidigm's descriptions of reflections that are "specular" or "shunted" light are consistent with the meaning of "light piping" as that term is used in the context of the Poeze patents, because Lumidigm recognizes that this light bypasses the measurement site inside the user's tissue. See JX-0001 at 22:48-50; RX-0411 at 7:66-8:7. This is also consistent with Mr. Kiani's testimony regarding "light piping," because the "shunted" light described in Lumidigm goes from the emitters to the detector without passing through the tissue. Tr. (Kiani) at 100:14-24 (goal is to avoid light that has not gone "through the tissue"). Moreover, Lumidigm expressly discloses that the placement

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of the detector creates an "optical blocking effect" that avoids "specular" or "shunted" light, *id.* at 7:66-8:10, and the evidence shows that this configuration would avoid light piping.

Apple also points to lateral surfaces in other prior art references, arguing that this limitation is obvious in combination with Seiko 131 or Cramer. Apple cites lateral surfaces around the photodiode disclosed in Seiko 131. RIB at 108 (citing RX-0666 at 10:30-36, Fig. 28). With respect to Cramer, Apple relies on the datasheet for the CLT 2160 detector, which was described by Dr. Warren as a "can detector" that "would be made from aluminum or stainless steel or some material that was impervious to light as a means to prevent light piping." Tr. (Warren) at 1231:23-1232:9, 1234:3-8; see RX-0670 at 5:33-35 ("A suitable detector is the type CLT 2160 photo diode produced by Clairex Electronics, Inc."); RX-1221 (CLT 2160 datasheet). Apple also cites Cramer's disclosure of "light blocking rings" that "isolate the photo detector from direct view from the light source and from view of the ambient light when the lower face is in contact with the wearer's body e.g. the wrist." RX-0670 at 2:46-51. One of these rings identified as "boss 22A prevents direct transmission of light between source 24 and detectors 23." Id. at 5:46-48. Apple further cites disclosures in Webster recognizing the problem of an "optical shunt," which is "when some of the light from the LEDs reaches the photodiode without passing through an arteriolar bed." RX-0035.0202. Webster recommends that "[o]ximeter probes should be manufactured of black opaque material that does not transmit light, or enclosed in an opaque plastic housing." Id.

Complainants argue that the alleged opaque lateral surfaces in Seiko 131 were not previously identified in Apple's prehearing brief or in any hearing testimony and are not supported by any teachings in Seiko 131. CRB at 63. With respect to Cramer, Complainants

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argue that there is no explicit disclosure of opaque material and further argue that the CLT 2160 datasheet is unreliable. *Id.* at 63-64.

Because the claimed opaque lateral surfaces are set forth in Lumidigm, it is unnecessary to address whether they are disclosed by Lumidigm in combination with Seiko 131 or Cramer. However, the undersigned agrees with Complainants that Apple has failed to identify any opaque lateral surfaces in Seiko 131.³⁷ With respect to Cramer, the undersigned agrees with Apple that one of ordinary skill in the art would have recognized that the CLT 2160 detectors have opaque lateral surfaces. *See* Tr. (Warren) at 1234:3-8; RX-1221.³⁸ Webster's reference to an "optical shunt" is consistent with the description of light piping discussed above.

Accordingly, the undersigned finds that the "opaque lateral surface" limitation of '501 patent claim 1 is disclosed in Lumidigm in the context of Lumidigm's wristwatch embodiment.

g. Element [1F]: "one or more processors configured to receive one or more signals from the photodiodes and calculate a measurement of the physiological parameter of the user"

With respect to the "one or more processors" limitation, Apple cites to Lumidigm's disclosure that its "portable electronic device comprises an electronic arrangement for performing a standard function of the portable electronic device, a biometric sensor, and a processor," and "[t]he processor is configured to operate the electronic arrangement to perform the standard function and to operate the biometric sensor." RX-0411 at 3:21-31; RIB at 77-79. Lumidigm further discloses that after light signals are detected, "the signals can be digitized and

³⁷ Regardless of whether Apple's contentions are timely, Apple's shading of unlabeled structures in Figure 28 of Seiko 131 that are allegedly opaque lateral surfaces does not appear to be supported by the evidence of record. *See* RIB at 108.

³⁸ The undersigned finds the CLT 2160 datasheet to be reliable evidence. Complainants have not identified any timely-raised objection to the admission of RX-1221, and this exhibit appears to be reliable on its face.

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recorded by standard techniques," and "[t]he recorded data can then be processed directly or converted." *Id.* at 9:58-62. A schematic for managing the functionality of the biometric sensor is illustrated in Figure 9, which depicts a "computer system" with "hardware elements that are electrically coupled via bus 342, which is also coupled with the biometric sensor 356." *Id.* at 12:56-66, Fig. 9. "The hardware elements include processor 332" and a "processing acceleration unit 346 such as a DSP or special-purpose processor." *Id.* at 12:66-13:14; *see* Tr. (Warren) at 1213:4-1214:1.

Complainants argue that Lumidigm fails to explicitly disclose that its processor calculates a measurement of a physiological parameter and does not explicitly describe a processor in the "wristwatch" embodiment. CRB at 49; see CIB at 124-29.

In consideration of the parties' arguments, the undersigned finds that Lumidigm meets the "one or more processors" limitation of '501 patent claim 1. Complainants' arguments were addressed above in the context of the preamble, and as discussed above, Lumidigm teaches that the "wristwatch" embodiment is one of the "portable devices" suitable for functionalities including the measurement of a physiological parameter. *See* RX-0411 at 3:35-47, 11:60-12:2, 19:18-28. With respect to the processing hardware depicted in Figure 9, Lumidigm explicitly notes that some of the components could be used in portable devices. *Id.* at 12:58-61. Moreover, a "processor" is explicitly claimed in Lumidigm as part of a "portable electronic device," where the processor "is further configured to operate the biometric sensor to perform a nonbiometric function," including a "spectrometer function," with examples provided of "an alcohol-monitor function, a bilirubin-monitor function," and "a hemoglobin-monitor function."

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Id. at 25:32-45 (claims 10, 11, 12).³⁹ Dr. Warren testified that this limitation is met by Lumidigm with respect to calculating a measurement of a physiological parameter. *See* Tr. (Warren) at 1213:4-1214:1. Accordingly, Lumidigm clearly discloses a "processor" that receives signals from a sensor and calculates a measurement of a physiological parameter.

The undersigned further finds that, to the extent Lumidigm does not disclose such a processor, one of ordinary skill in the art would have had a reason to implement such calculations and a reasonable expectation of success in Lumidigm's "wristwatch" embodiment, because Lumidigm explicitly notes that its extended functionality is "especially suitable" for mobile devices. *See id.* at 17:67-18:2.

Accordingly, the undersigned finds that the "one or more processors" limitation of '501 patent claim 1 is met by Lumidigm.

h. Element [12]: "wherein the convex surface of the protrusion is an outermost surface configured to contact the tissue of the user and conform the tissue into a concave shape"

Claim 12 of the '501 patent depends from claim 1, further requiring that "the convex surface of the protrusion is an outermost surface configured to contact the tissue of the user and conform the tissue into a concave shape." As discussed above in the context of the "protrusion" limitation of '501 patent claim 1, the undersigned finds that a convex protrusion is neither explicitly nor inherently disclosed in Lumidigm but that one of ordinary skill in the art would have reason to modify Lumidigm's optical surface to form a convex protrusion.

Apple contends that this limitation is obvious in view of Lumidigm alone or in combination with Seiko 131 or Cramer, because a person of ordinary skill in the art would have

³⁹ As discussed above in the context of the preamble, there is a presumption that these functions are enabled, and Complainants have not provided evidence rebutting Lumidigm's enablement of measurements for physiological parameters other than blood oxygen.

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understood that a convex protrusion would conform the user's tissue into a concave shape. RIB at 79, 106. Dr. Warren described the limitation in claim 12 as "an obvious statement," recognizing that "if you have a convex surface and you position it next to tissue, any pressure at all will conform the tissue into a concave shape." Tr. (Warren) at 1214:2-11. Complainants do not raise any arguments with respect to claim 12 that are significantly different from those addressed above in the context of claim 1. See CRB at 46-47, 71-73. Accordingly, in view of the unrebutted testimony of Dr. Warren, the undersigned finds that one of ordinary skill in the art would have known that a convex surface in contact with the tissue of the user would conform the tissue into a concave shape.

As discussed above, Lumidigm explicitly discloses a user-worn wristwatch device configured to non-invasively measure physiological parameters of a user that meets the limitations of claim 1 requiring at least three LEDs, at least three photodiodes, a plurality of openings for each photodiode with opaque lateral surfaces, and a processor configured to calculate measurements of physiological parameters, and the evidence shows that one of ordinary skill in the art would have reason to modify the optical surface of the sensor head in Lumidigm's wristwatch to form the claimed protrusion comprising a convex surface based on Lumidigm's explicit suggestion of a sensor head with a "compound curvature" for "technical or stylistic reasons." RX-0411 at 7:57-63. For these and the other reasons discussed above, the evidence thus shows that a combination of elements disclosed in Lumidigm and known in the prior art would have yielded a wristwatch meeting each limitation of claims 1 and 12, and one of ordinary skill in the art would have had a reasonable expectation of success in making such a combination. Further, as discussed infra, secondary considerations of non-obviousness do not

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weigh significantly against a finding that claim 12 of the '501 patent is obvious. Accordingly, the undersigned finds that claim 12 of the '501 patent is invalid as obvious.

2. '502 Patent Claim 22

As discussed below, the evidence fails to clearly and convincingly show that claim 22 of the '502 patent is rendered obvious by Lumidigm alone or in combination with other prior art.

a. Element [19 preamble]: "A user-worn device configured to non-invasively measure an oxygen saturation of a user, the user worn device comprising:"

The preamble of '502 patent claim 19 requires "[a] user-worn device configured to non-invasively measure an oxygen saturation of a user." As discussed above in the context of the preamble of '501 patent claim 1, Lumidigm discloses a user-worn wristwatch embodiment with a biometric sensor configured to measure a physiological parameter. *See* RX-0411 at 3:35-47, 11:60-12:2, 19:18-28, claim 12. With respect to measuring oxygen saturation, Apple cites Lumidigm's teaching that "changes in blood flow cause spectroscopic changes that may be detected" with its biometric sensor, noting that "these spectroscopic changes are correlated with oxygenation and/or hemoglobin levels in the blood." RX-0411 at 19:22-26. Apple relies on Dr. Warren's opinion that one of ordinary skill in the art would have been able to implement pulse oximetry functionality in Lumidigm's wristwatch. Tr. (Warren) at 1216:10-25. Dr. Warren points to efforts by his students to measure blood oxygen at the wrist as early as 2002, *id.* at 1195:24-1196:10, and Apple cites prior art reflectance pulse oximeters that existed decades before the Poeze patents. *See* RX-0484.

Complainants argue that Lumidigm's disclosure is insufficient to teach a blood oxygen measurement in a wristwatch. CIB at 126-29; CRB at 44-46. Dr. Madisetti characterizes Lumidigm's description of an oxygen saturation measurement as "vague" and "aspirational." Tr.

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(Madisetti) at 1330:20-1331:11. Complainants further argue that a person of ordinary skill would not have known how to implement the measurement of oxygen saturation or any other physiological parameter in Lumidigm's wristwatch embodiment and that Lumidigm provides no motivation for doing so. CIB at 128-29; Tr. (Madisetti) at 1340:20-1341:14. Complainants argue that implementing such functionalities in a wristwatch would not have a reasonable expectation of success, citing testimony from Apple engineers expressing skepticism that blood oxygen could be measured at the wrist. CIB at 129. Complainants cite evidence that Apple took

. See CRB at 86-87.

In reply, Apple argues that using Lumidigm's wristwatch to measure a physiological parameter such as blood oxygen would have been obvious to one of skill in the art. RRB at 51-52. Apple cites evidence that Dr. Warren experimented with measuring pulse oximetry on the wrist with his students at Kansas State University in 2002. Tr. (Warren) at 1195:24-1196:10, 1216:10-25; RX-0632 (2002 photograph); RX-0504 (2005 poster); RX-0508 (2005 article). Apple submits that the development timeline for implementing pulse oximetry in the Apple Watch is not relevant to the obviousness of the Poeze patents, because the

RIB at

144-46; RRB at 68-69.

In consideration of the parties' arguments, the undersigned finds that the evidence of record fails to show that one of ordinary skill would have been enabled to measure oxygen saturation in the Lumidigm wristwatch. As discussed above in the context of the '501 patent, Lumidigm describes "extended functionality" including measurements of "oxygenation and/or hemoglobin levels in the blood," and states that such functionalities are "especially suitable when the biometric sensor is comprised by a portable device, such as a portable electronic device."

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RX-0411 at 17:64-18:2, 19:18-28. The specification explicitly identifies "a watch" as an example of a "portable electronic device having extended functionality." *Id.* at 3:21-37. Lumidigm thus contemplates blood oxygen measurement in a wristwatch as one implementation of its "extended functionality," but the Federal Circuit has held that "when the prior art includes a method that appears, on its face, to be capable of producing the claimed composition," the patentee may rebut this evidence by presenting "sufficient reason or authority or evidence, on the facts of the case, to show that the prior art method would not produce or would not be expected to produce the claimed subject matter." *In re Kumar*, 418 F.3d 1361, 1368 (Fed. Cir. 2005); Part IV.G.1.a *supra* (discussing additional relevant authority).

In rebuttal to Lumidigm's blood oxygen disclosure, Complainants have presented persuasive evidence that persons of ordinary skill in the art would not have expected to successfully measure blood oxygen in a wristwatch at the time of the Poeze patents. *See* CIB at 126-29; CRB at 44-46. Mr. Rowe, the "primary inventor" of Lumidigm, *see* Tr. (Rowe) at 1146:18-1147:3, acknowledged that he never made a device that calculated blood oxygen at Lumidigm, Inc. CX-0297C (Rowe Dep. Tr.) at 118:4-119:8. Complainants have also cited testimony from numerous Apple engineers describing the significant difficulty of performing pulse oximetry at the wrist. *See* Tr. (Mannheimer) at 1012:12-1013:6 (admitting that in 2014, he believed that pulse oximetry at the wrist would be a challenge, that he "did not know if it could be done," that "the wrist is just enormously different from the physiological perspective," and

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⁴⁰ There is little to no technical description of the blood oxygen functionality in Lumidigm, let alone in the wristwatch embodiment specifically. *See* CIB at 126; RX-0411 at 19:24-28.

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that the signal at the wrist is "enormously weak") ⁴¹ ; see also id. at 998:21-999:6 (products he
previously worked on "operated on a much more vascularized tissue bed, usually fingers or
forehead [t]he wrist is "just an incredibly different beast"); CX-0299C (Waydo Dep. Tr.) at
166:4-167:5 ("The wrist is one of the most difficult places on the body to do almost every
physiological measurement"); CX-0295C (Shui Dep. Tr.) at 108:13-21 ("
. The watch is
worn on the wrist, and the wrist is well known for its lack of signal."). The blood oxygen
measurement described in Lumidigm is characterized as relying on "spectrographic changes that
may be detected" by its biometric sensor, which are "correlated with oxygenation and/or
hemoglobin levels." RX-0411 at 19:22-26. The testimony of Apple engineers shows the
difficulty in calculating blood oxygen from such spectra if obtained at the wrist,
; Tr. (Land) at 983:2-12
; see CIB at 169-171.

Apple counters this evidence with Dr. Warren's testimony describing pulse oximetry experiments at Kansas State University in 2002-05, RRB at 52-53, but there is little evidence that wrist-based blood oxygen levels were successfully measured in a watch-type environment. With

⁴¹ Dr. Mannheimer had worked on pulse oximetry technology at Nellcor from 1987 to 2008, before joining Apple. *See* Tr. (Mannheimer) at 994:9-25, 1009:2-8. He was hired by Apple because of his "extensive experience" in pulse oximetry and biosensing in general. Tr. (Land) at 963:10-15.

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respect to the work done with Professor Warren's undergraduate students cited by Respondents (*see* RRB at 52), Dr. Warren testified that his students "worked with [these sensors] on their wrists" (Tr. at 1216:23-25) and took measurements from various locations on the body, including wrists (Tr. at 1186:8-16, 1196:8-10, RDX-8.88). He provided no testimony regarding the results of those measurements. Apple also does not identify measurements of oxygen saturation at the wrist in the corroborating documents provided by Dr. Warren. *See* RIB at 64-67; RRB at 52-53; CRB at 45-46; RX-0504 (referencing wrist as a "viable" measuring site but only presenting data from finger and head); RX-0508.0007, .0012 (referencing "different body locations (*e.g.*, wrist, forehead or ear lobe) that have noticeably different vascular profiles" and presenting data from the thumb). Apple also argues that methods for pulse oximetry were well-known at the time of the Poeze patents, RRB at 51, but Apple's evidence for prior art blood oxygen measurements relies on measurements at other locations on the body—not at the wrist. *See, e.g.*, RX-0484 (describing measurement of blood oxygen at the finger). ^{42,43}

On the evidence of record, the presumption of enablement is overcome with respect to configuring Lumidigm's wristwatch to measure blood oxygen at the time of the Poeze patents.

⁴² Apple argues that its engineers' testimony related solely to "adding that known functionality into the limited space of a small consumer device" (RRB at 47), but the testimony at issue indicates broader signal issues.

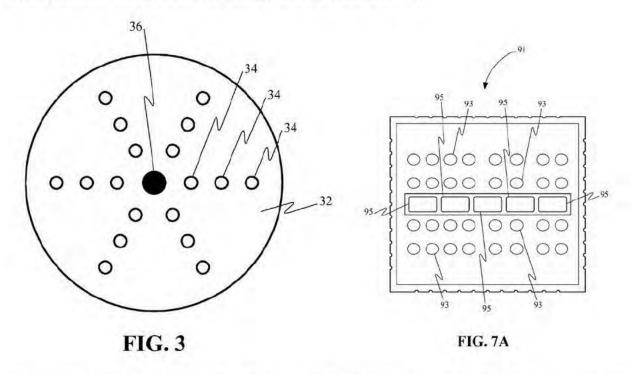
⁴³ Mr. Kiani testified at the hearing that he could have done a "conventional pulse oximeter" on the wrist "30 years ago" (Tr. (Kiani) at 114:20-22), but this testimony is less persuasive on this issue than the testimony of the Apple engineers, particularly given Mr. Kiani's testimony that many conventional pulse oximetry devices do not work. *See* Tr. (Kiani) at 102:20-21, 121:18-24. As discussed above, Apple documents

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Accordingly, Apple has not shown that the preamble limitations of '502 patent claim 19 are met by Lumidigm.⁴⁴

b. Element [19A]: "a plurality of emitters configured to emit light, each of the emitters comprising at least two light emitting diodes (LEDs)"

There is no dispute that Lumidigm discloses a plurality of emitters. *See* RIB at 80-82; CIB at 123. As discussed above in the context of the LEDs limitation of '501 patent claim 1, Lumidigm discloses "a plurality of light sources" that "may comprise light emitting diodes ('LEDs')," including "sets of LEDs." RX-0411 at 6:22-53. Lumidigm discloses several configurations with light sources arranged in sets of at least two:



Id. at 8:33-42 (Fig. 3), 9:26-34 (Fig. 7A); *see also* RIB at 81 (identifying Figs. 3, 5, 7A, and 7B). Lumidigm explicitly discusses the benefits of pairs of light sources, noting that two light sources

⁴⁴ The evidence regarding the difficulty in achieving blood oxygen measurements at the wrist, as discussed above, also shows the lack of clear and convincing evidence of a reasonable expectation of success for the asserted obviousness arguments.

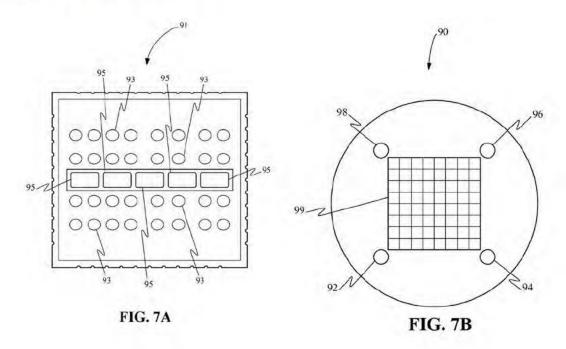
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having the same wavelength "can be combined to increase the resulting signal-to-noise ratio of the measurement," while two light sources with different wavelengths can "provide unique and useful information about the tissue optical properties." *Id.* at 7:34-53.

c. Element [19B]: "four photodiodes arranged within the userworn device and configured to receive light after at least a portion of the light has been attenuated by tissue of the user"

As discussed above in the context of the "photodiodes" limitation of '501 patent claim 1, the evidence shows that Lumidigm discloses silicon detectors that are photodiodes, and the sensor geometries disclosed in Lumidigm's specification can be used in the "wristwatch" embodiment in a configuration for receiving light that has been attenuated by tissue of the user.

See RX-0411 at 6:56-63, 11:65-12:2. Lumidigm discloses two specific configurations with arrays of at least four detectors:



Id. at 9:26-45, Fig. 7A, Fig. 7B; Tr. (Warren) at 1221:10-15; RDX-8.37; RIB at 82. Lumidigm describes the benefits of such detector arrays, wherein "[t]he signal detected at each of the array

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elements then represents a different source-detector separation with respect to the light from a given light source." *Id.* at 9:39-41.

d. Element [19C]: "a protrusion comprising a convex surface including separate openings extending through the protrusion and lined with opaque material, each opening positioned over a different one associated with each of the four photodiodes, the opaque material configured to reduce an amount of light reaching the photodiodes without being attenuated by the tissue"

As discussed above in the context of the "protrusion" limitation of '501 patent claim 1, Lumidigm's disclosures provide a reason to modify the optical surface of Lumidigm to form a protrusion comprising a convex surface. *See* Part IV.E.1.d. However, the evidence does not clearly and convincingly show how or why the "array"-type detectors in Lumidigm relied upon by Apple for Element [19B] would be formed with separate openings through the protrusion for individual photodiodes in the array. *See* RIB at 82; CIB at 143 (noting requirement to treat each claim as an integrated whole); CRB at 55 (same). For this limitation, Apple simply refers to the reasoning provided for the three-photodiode configuration relied upon for Element [1B] (which relies on the single diode example in Figure 2 of Lumidigm), but that configuration does not appear similar to the "array" configurations cited by Respondents for Element [19B], and no clear and convincing testimony linking Figs. 7A and 7B to separate "openings" through the protrusion for individual (or subsets of) diodes in an array has been provided. 45 *See* RIB at 72-

⁴⁵ Lumidigm explains that "detector 36" may be "a single element, a plurality of discrete elements, or a one- or two-dimensional array of elements." RX-0411 at 6:54-56. Fig. 2 shows a single opening over detector 36 which, if anything, would appear to suggest a single opening over an array, rather than separate openings over individual diodes in the array. While Apple argues that the Figs. 7A and 7B are merely "illustrative," and that Lumidigm's sensor "can include any number and arrangement of photodiodes" (RIB at 82), Apple did not clearly present any other specific LED/photodiode arrangement in its analysis of Element [19B] for assessment in view of the claim as a whole. *See* Tr. (Warren) at 1221:10-15 and RDX-8.37; RIB at 82.

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74, 83-84; RX-0411 at 9:26-45 (discussing the "detector array" structure); CIB at 143 (arguing that Apple does not show obviousness based on claim as an integrated whole).

With regard to Figure 7B, Dr. Warren testified with regard to a different limitation that "one of ordinary skill could essentially choose any four of the photodiodes within this arrangement . . . and then include an opening over each one" (Tr. (Warren) at 1225:23-1226:1) but this testimony of what one of ordinary skill in the art could theoretically do is insufficient to clearly and convincingly show that Lumidigm discloses this arrangement, or provide a reason for one of ordinary skill in the art to modify Lumidigm to do so. *See Adidas AG v. Nike, Inc.*, 963 F.3d 1355, 1359 ("The obviousness inquiry does not merely ask whether a skilled artisan could combine the references, but instead asks whether 'they would have been motivated to do so."").

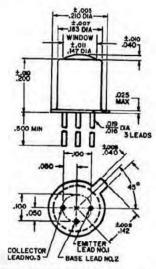
Apple also argues that Element [19C] is rendered obvious based on a combination with Cramer, which Apple contends includes four diodes in a circular array, with separate openings with opaque lateral surfaces positioned over each of the photodiodes. *See* RIB at 108-110. As discussed above in Part IV.E.1.d, the evidence does not clearly and convincingly show that one of skill in the art would have a reason to combine the specific structures of Cramer with Lumidigm, and Cramer only includes one LED (which would not meet the "plurality of emitters" requirement of Element [19A]). *See* n.36 *supra*.

e. Element [19D]: "optically transparent material within each of the openings"

With respect to the "optically transparent material" limitation of '502 patent claim 19, Apple identifies Lumidigm's disclosure of "an optical relay (not shown) between the sensor surface 39 and the skin 40" that "transfers the light . . . from the skin back to the detector(s)." RX-0411 at 8:19-23; RIB at 84-85. Lumidigm provides examples of these optical relays, including "fiber-optic face plates and tapers, individual optical fibers and fiber bundles, light

pipes and capillaries, and other mechanisms known to one of skill in the art." *Id.* at 8:23-26. Dr. Warren testified at the hearing that one of ordinary skill in the art would understand an "optical relay" to be an optically transparent material. Tr. (Warren) at 1221:16-1222:25; RIB at 84-85.

Apple further argues that this limitation would be obvious because the use of transparent materials within openings was well-known at the time of the Poeze patents. RIB at 111-113; Tr. (Warren) at 1193:23-1194:14, 1221:16-1222:9; RDX-8C.11 (citing RX-0670; RX-0665; RX-0666; RX-0667; RX-0648). Apple also points to the "light transmittance plate" disclosed in Seiko 131, wherein "[a] transparent window is formed on the top of sensor frame 36... by means of light transmittance plate 34, which is a glass plate." RX-0666 at 10:30-32. With respect to Cramer, Apple identifies the datasheet for the CLT 2160, which depicts a "window on top of can." RX-1221; see RX-0670 at 5:33-35.



PHYSICAL DIMENSIONS — in accordance with JEDEC (T018) outline except for window on top of can.

All dimensions in inches. Collector electrically connected to case. Leads gold plated Kovar. Case: 24-1285 Document: 66-4 Page: 147 Filed: 08/07/2024 PUBLIC VERSION

RX-1221. Apple further argues that Cramer discloses a further layer of clear transparent windows between the detectors and the skin. Tr. (Warren) at 1234:22-1235:12; RDX-8C.73 (citing RX-0670 at Fig. 6).

Complainants argue that Lumidigm's disclosure of an "optical relay" does not meet the "optically transparent material" limitation and is not disclosed in connection with Lumidigm's "wristwatch" embodiment. CIB at 138-39. Dr. Madisetti does not agree with Dr. Warren's opinions with respect to this limitation. *See* Tr. (Madisetti) at 1330:2-5. 46 Complainants argue that Seiko 131 fails to disclose multiple openings or optically transparent material within multiple openings. CIB at 148-49. Complainants argue that with respect to Cramer, the alleged windows are between the annular rings and are not "within" the openings. CIB at 146-47.

In consideration of the parties' arguments, the undersigned finds that Lumidigm clearly discloses "optically transparent material" over openings associated with photodiodes, but the evidence does not clearly and convincingly show a reason to incorporate such material "within" each opening. Lumidigm describes an optical relay that is comprised of optically transparent material. *See* RX-0411 at 8:19-26; *see* Tr. (Warren) at 1221:16-1222:25. The optical relay in Lumidigm is not "within" the opening depicted in Figure 2, however—it is located "between the sensor surface 39 and the skin 40." RX-0411 at 8:19-26, Fig. 2.⁴⁷ Apple appears to have

⁴⁶ Complainants argue that Apple should be precluded from arguing that Lumidigm discloses a "lens" because this contention was not disclosed in Apple's pre-hearing brief, RIB at 138-39, but there was no objection to Dr. Warren's testimony regarding a "lens" at the hearing, and Apple explains that the testimony merely represents Dr. Warren's opinion that one of ordinary skill in the art would understand Lumidigm's "optical relay" to be a "lens." RRB at 57-58.

⁴⁷ Seiko 131 similarly discloses a "light transmittance plate" that is positioned above its sensor but is not "within" any opening. *See* RX-0666 at 10:30-32. Cramer also discloses annular windows that do not appear to be associated within "each" opening. *See* Tr. (Warren) at 1234:22-1235:12; RDX-8C.73 (citing RX-0670 at Fig. 6).

identified transparent windows within an opening in Cramer's preferred photodiode, the CLT 2160, but did not provide a clear and convincing reason to modify Lumidigm to include such material within the openings or to incorporate the CLT 2160 photodiode in Lumidigm. *See* RX-0670 at 5:33-35, Fig. 6; RX-1221; RIB at 112-113. 48,49

f. Element [19E]: "one or more processors configured to receive one or more signals from at least one of the four photodiodes and output measurements responsive to the one or more signals, the measurements indicative of the oxygen saturation of the user"

As discussed above in the context of the preamble limitations, the evidence indicates that one of skill in the art would not have been enabled to use the Lumidigm wristwatch embodiment to measure oxygen saturation. In particular, Lumidigm only discloses that spectroscopic changes correlated with oxygenation "may be detected according to the methods described above." RX-0411 at 19:22-26. Complainants have presented credible evidence that one of ordinary skill in the art would not have been able to successfully implement this detection in a wristwatch at the time of the Poeze patents. *See* CIB at 126-29; CRB at 44-46. Accordingly, for the same reasons discussed above in the context of the preamble, Apple has not shown by clear and convincing evidence that the "one or more processors" limitation of '502 patent claim 19 is met by Lumidigm.

⁴⁸ As discussed above in the context of the "opaque lateral surfaces" limitation of '501 patent claim 1, the undersigned finds the CLT 2160 datasheet to be reliable evidence for the structure of the photodiode disclosed in Cramer. *See* Part IV.G.1.f *supra*.

⁴⁹ Apple identifies a similar "can package" photodiode with a window described in Webster. RX-0035.0094-95 ("In the can package . . ., the photodiode chip is mounted on a metallic stem and is sealed with a cap that has a window to allow incident light to reach the semiconductor surface.").

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g. Element [20]: "further comprising a thermistor"

Claim 20 of the '502 patent depends from claim 19, further requiring a thermistor. With respect to this limitation, Apple identifies Lumidigm's disclosure of "preprocessing steps" including "performing explicit corrections to account for sensor-to-sensor variations or environmental influences of temperature, humidity, and pressure." RX-0411 at 14:21-28. Lumidigm notes that "[t]hese and other techniques are well known in the art," id. at 14:29, and Dr. Warren testified that "a person of ordinary skill would realize that such a temperature measurement could easily be done with a thermistor." Tr. (Warren) at 1223:1-20. Apple identifies examples of suitable thermistors in Webster, which explicitly discloses a thermistor to compensate for LED temperature changes: "One way to compensate for LED temperature changes is to have a temperature sensor built into the probe along with the LEDs and photodiode." RX-0035.0085 (citation omitted). A thermistor is also identified as part of an oxygen sensor in a different chapter of Webster. *Id.* at 42. Apple submits that one of ordinary skill in the art would have been motivated to use one of the thermistors disclosed in Webster in Lumidigm's wristwatch embodiment with a reasonable expectation of success. RIB at 123-24; Tr. (Warren) at 1239:22-1240:3.

Complainants argue that Lumidigm fails to disclose or suggest a thermistor. See CIB at 140. With respect to Webster, Complainants submit that the two thermistors identified by Apple are in separate chapters describing different devices. Id. at 153-54; see Tr. (Madisetti) at 1336:5-18.

In consideration of the parties' arguments, the undersigned finds that Lumidigm includes an explicit suggestion to account for environmental influences including temperature in the operation of its biometric sensor, *see* RX-0411 at 14:21-28, and Apple has shown that one of

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ordinary skill in the art would have had reason to use a thermistor to achieve this goal. See Tr. (Warren) at 1223:1-20. Moreover, the undersigned finds that one of ordinary skill in the art would have had a reasonable expectation of success adding a thermistor to Lumidigm's wristwatch embodiment, because it involves "the mere application of a known technique to a piece of prior art ready for the improvement." KSR, 500 U.S. at 417. In the context of accounting for environmental influences, Lumidigm recognizes that "[t]hese and other techniques are well known in the art," id. at 14:29, and this is corroborated by Webster, which describes the use of a thermistor to "compensate for LED temperature changes." RX-0035.0085. In a separate chapter, Webster also discloses a thermistor that is used with an oxygen sensor. *Id.* at 42. The undersigned agrees with Complainants that Apple has failed to show that any of the thermistors disclosed in Webster could be directly implemented in Lumidigm's device, but "it is not necessary that [two pieces of prior art] be physically combinable to render obvious" the asserted patent. Allied Erecting and Dismantling Co., Inc. v. Genesis Attachments, LLC, 825 F.3d 1373, 1381 (Fed. Cir. 2016) (quoting In re Sneed, 710 F.2d 1544, 1550 (Fed. Cir. 1983)). The disclosures in Webster provide clear evidence that thermistors would have been known to persons of ordinary skill in the art to measure the temperature described in Lumidigm.

> h. Element [21]: "wherein the one or more processors are further configured to receive a temperature signal from the thermistor and adjust operation of the user-worn device responsive to the temperature signal"

Claim 21 of the '502 patent depends from claim 20, further requiring that "the one or more processors are further configured to receive a temperature signal from the thermistor and adjust operation of the user device responsive to the temperature signal." The evidence shows that this limitation to be met for the same reasons discussed above in the context of '502 patent claim 20. In particular, Lumidigm explicitly discloses "preprocessing steps" including

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"performing explicit corrections to account for sensor-to-sensor variations or environmental influences of temperature, humidity, and pressure." RX-0411 at 14:21-28. One of ordinary skill in the art would have recognized that these preprocessing steps would have been performed by the processor disclosed in Lumidigm, as discussed above in the context of the "one or more processors" limitation, using a temperature signal from a thermistor, as discussed above in the context of '502 patent claim 20.

i. Element [22]: "wherein the plurality of emitters comprise at least four emitters, and wherein each of the plurality of emitters comprises a respective set of at least three LEDs"

Claim 22 of the '502 patent depends from claim 21, further requiring that "the plurality of emitters comprise at least four emitters, and wherein each of the plurality of emitters comprises a respective set of at least three LEDs." As discussed above in the context of the "plurality of emitters" limitation, Lumidigm discloses "a plurality of light sources" that "may comprise light emitting diodes ('LEDs')," including "sets of LEDs." RX-0411 at 6:22-53. Figure 7A of Lumidigm discloses an embodiment with four sets of eight LEDs. *Id.* at 9:26-34 (Fig. 7A). *See* Tr. (Warren) at 1220:13-1221:6; RDX-8.36. As discussed above, the Figure 7A embodiment also meets the "four photodiodes" requirement of element [19B]. *See* RDX-8.37 (identifying Figure 7A and 7B as meeting the four photodiodes limitation).

* * *

For the reasons discussed above, the evidence fails to clearly and convincingly disclose a combination of elements meeting the limitations of claim 22 of the '502 patent, and Apple has not shown a reasonable expectation of success in achieving a combination of these elements in Lumidigm's wristwatch embodiment.

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'502 Patent Claim 28

As discussed below, the evidence fails to clearly and convincingly show that claim 28 of the '502 patent is rendered obvious by Lumidigm alone or in combination with other prior art.

a. Element [28 preamble]: "A user-worn device configured to non-invasively measure an oxygen saturation of a user, the user worn device comprising:"

For the same reasons discussed above in the context of the preamble limitations of '502 patent claim 19 (Element 19 [Preamble]), the preamble limitations of '502 patent claim 28 are not met by Lumidigm because one of ordinary skill in the art would not have been enabled to measure oxygen saturation using the Lumidim watch embodiment.

b. Element [28A]: "a first set of light emitting diodes (LEDs), the first set of LEDs comprising at least an LED configured to emit light at a first wavelength and an LED configured to emit light at a second wavelength"

With respect to the first LEDs limitation of '502 patent claim 28, Apple identifies

Lumidigm's disclosure that its light sources "can each have the same wavelength characteristics or can be comprised of sources with different center wavelengths in a spectral range from about 300 nm to about 10,000 nm." RX-0411 at 6:43-46; RIB at 88-90. Lumidigm provides that "the collection of light sources 34 can include some sources that have the same wavelengths as others and some sources that are different." *Id.* at 6:46-48. Lumidigm explicitly discusses the benefits of pairs of light sources, noting that two light sources having the same wavelength "can be combined to increase the resulting signal-to-noise ratio of the measurement," while two light sources with different wavelengths can "provide unique and useful information about the tissue optical properties." *Id.* at 7:34-53. There is no dispute that Lumidigm thus discloses LEDs emitting at different wavelengths, and Apple identifies the sensor geometries in Figs. 3, 5-6, and 7A-B of Lumidigm as meeting this limitation. RIB at 89-90. Lumidigm provides that "any of

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the sensor geometries previously disclosed or other equivalent configurations can be used" in the wristwatch embodiment. *Id.* at 11:65-12:2.

c. Element [28B]: "a second set of LEDs spaced apart from the first set of LEDs, the second set of LEDs comprising at least an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength"

With respect to the second LEDs limitation of '502 patent claim 28, Apple identifies Lumidigm's disclosure of "sets of LEDs . . . with differing wavelength characteristics that lie within the spectral range from about 350 nm to about 1100 nm." RX-0411 at 6:48-55.

Lumidigm explicitly discusses the benefits of pairs of light sources, noting that two light sources having the same wavelength "can be combined to increase the resulting signal-to-noise ratio of the measurement," while two light sources with different wavelengths can "provide unique and useful information about the tissue optical properties." *Id.* at 7:34-53. Apple further cites U.S. Patent Application No. 10/262,403, which is incorporated by reference in Lumidigm, *see* RX-0411 at 1:40-44, and explicitly discloses multiple sets of LEDs with the same wavelengths emitted by LEDs in each set. *See* RX-0460 at ¶ 54, Fig. 6. There is no dispute that Lumidigm thus discloses a second set of LEDs emitting at the same wavelengths as the first set of LEDs, and Apple identifies the sensor geometries in Figs. 3, 5-6, and 7A-B of Lumidigm as meeting this limitation. Lumidigm states that in "any of the sensor geometries previously disclosed or other equivalent configurations can be used" in the wristwatch embodiment. *Id.* at 11:65-12:2.

d. Element [28C]: "four photodiodes arranged in a quadrant configuration on an interior surface of the user-worn device and configured to receive light after at least a portion of the light has been attenuated by tissue of the user"

As discussed above in the context of the "photodiodes" limitations of '501 patent claim 1 and '502 patent claim 19, the undersigned finds that Lumidigm discloses silicon detectors that

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are photodiodes. *See* RX-0411 at 6:56-63, 9:26-45. With respect to the claimed "quadrant configuration," Apple points to Lumidigm's Figure 7B, where detectors are arranged in a two-dimensional array. *See* Tr. (Warren) at 1225:13-1226:1; RDX-8C.44; RX-0411 at 9:34-45, Fig. 7B; RIB at 91.

e. Element [28D]: "a thermistor configured to provide a temperature signal"

As discussed above in the context of '502 patent claims 20 and 21, the undersigned finds that Lumidigm, in combination with Webster, provides a reason to modify Lumidigm to include a thermistor and shows a reasonable expectation of success. *See* RX-0411 at 14:21-28; RX-0035.0085.

f. Element [28E]: "a protrusion arranged above the interior surface, the protrusion comprising: a convex surface"

As discussed above in the context of the "protrusion" limitation of '501 patent claim 1, the undersigned finds that one of skill in the art would have reason to modify Lumidigm to achieve this limitation, and a reasonable expectation of success. *See* RX-0411 at 4:54-56, 8:1-10, Fig. 2; RX-0666 at 19:5-8, Fig. 28; RX-0670 at 5:45-51, Fig. 3, Fig. 6.

g. Element [28F]: "a plurality of openings in the convex surface, extending through the protrusion, and aligned with the four photodiodes, each opening defined by an opaque surface configured to reduce light piping"

As discussed above in the context of the "plurality of openings" limitation of claim 22 (Element [19C]), the evidence fails to clearly and convincingly show a plurality of openings aligned with the four photodiodes in the context of the "four photodiode" embodiments relied upon by Apple for Element [28C].

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h. Element [28G]: "a plurality of transmissive windows, each of the transmissive windows extending across a different one of the openings"

As discussed above in the context of the "optically transparent material" limitation of '502 patent claim 19 (Element [19D]), Lumidigm clearly discloses an "optical relay" that is transmissive and is positioned above an opening for a detector. *See* RX-0411 at 8:19-26; *see* Tr. (Warren) at 1221:16-1222:25. Lumidigm discloses a single window, but Dr. Warren suggests that "a person of skill would know that you could do an individual faceplate for each of the individual openings as a means to provide light but still optimize the process." Tr. (Warren) at 1221:1-1222:25. Dr. Warren identifies several prior art references with such windows extending across openings over photodiodes. *Id.* at 1193:23-1194:14; RDX-8C.11 (citing RX-0670; RX-0666; RX-0667).

i. Element [28H]: "at least one opaque wall extending between the interior surface and the protrusion, wherein at least the interior surface, the opaque wall and the protrusion form cavities, wherein the photodiodes are arranged on the interior surface within the cavities"

For the reasons discussed above in the context of the "opaque lateral surface" limitation of '501 patent claim 1 and the "opaque material" limitation of '502 patent claim 19 (Elements [1E] and [19C]), the undersigned finds Lumidigm, in combination with the other prior art, discloses the requirements of this limitation. *See* RX-0411 at 7:66-8:11, Fig. 2; RX-0670 at 2:46-51, 5:33-35, 5:46-48, Fig. 3, Fig. 6; RX-1221.

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j. Element [28I]: "one or more processors configured to receive one or more signals from at least one of the photodiodes and calculate an oxygen saturation measurement of the user, the one or more processors further configured to receive the temperature signal"

As discussed above in the context of the "one or more processors" limitation of '502 patent claim 19 (Element [19E]), Lumidigm does not disclose a processor configured to calculate an oxygen saturation measurement. ^{50,51}

k. Element [28J]: "a network interface configured to wirelessly communicate the oxygen saturation measurement to at least one of a mobile phone or an electronic network"

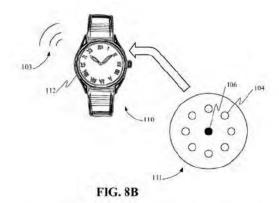
With respect to the "network interface" limitation, Apple identifies a "communications system 344" disclosed in Lumidigm and depicted on Figure 9, which "may comprise a wired, wireless, modem, and/or other type of interfacing connection and permits data to be exchanged with external devices." RX-0411 at 13:9-12, Fig. 9. In the context of a key fob embodiment, Lumidigm discloses "short-range wireless techniques based upon RF signals 103 . . . to communicate between the fob and a corresponding reader." *Id.* at 11:38-42. In this embodiment, the transmission can be "a simple confirmed or denied signal" or "the most recent measured spectrum is transmitted to the reader and the comparison and decision is accomplished at the reader or at a host to which the reader is connected." *Id.* at 11:49-55. Apple further

⁵⁰ As discussed above in the context of the "one or more processors" limitation of '501 patent claim 1 (Element [1F]), Lumidigm does disclose a "processor" that receives signals from a sensor and outputs measurements indicative of physiological parameters. *See* RX-0411 at 12:56-13:14.

⁵¹ As discussed above in the context of the "thermistor" limitations of '502 patent claims 20 and 21 (Elements [20] and [21]), the evidence shows that one of ordinary skill in the art would have reason to incorporate a thermistor in the Lumidigm wristwatch embodiment. *See* RX-0411 at 14:21-28; RX-0035.0085.

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submits that "RF signals 103" are depicted in Figure 8B in the context of the wristwatch embodiment.



Id. at Fig. 8B; RIB at 94-95. Complainants dispute whether Lumidigm discloses this limitation in combination with the wristwatch embodiment and/or the extended functionality for measuring physiological parameters. CIB at 141-42; CRB at 51.

In consideration of the parties' arguments, the undersigned finds that Lumidigm clearly discloses a network interface for wireless communication with an electronic network in its wristwatch embodiment. *See* RX-0411 at 11:38-55, Fig. 8B. This does not include the communication of an oxygen saturation measurement, however, because no such measurement is disclosed in Lumidigm, for the reasons discussed above in the context of the preamble of '502 patent claim 19 (Element [19 preamble]).

 Element [28K]: "a user interface comprising a touch-screen display, wherein the user interface is configured to display indicia responsive to the oxygen saturation measurement of the user"

With respect to the "user interface comprising a touch-screen display" limitation, Apple points to Lumidigm's disclosure of embodiments of "a personal electronic device that may be configured with biometric capability in the form of a PDA" and "a combined cellular telephone/PDA." RX-0411 at 12:21-48, Fig. 8D, Fig. 8E. Apple argues that such devices were

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known to have touchscreen displays. RIB at 95-96; *see* Tr. (Warren) at 1226:23-1227:3. Apple further cites an embodiment disclosed in Lumidigm wherein the portable electronic device can access the internet "to display the retrieved information on the portable electronic device." RX-0411 at 21:29-33. Apple further asserts the widespread availability of touch-screen user interfaces, and Dr. Warren testified that a person of ordinary skill would have been able to incorporate a touch-screen into any portable device. RIB at 129-33; *see* Tr. (Warren) at 1226:23-1227:5. Apple identifies a touch-screen disclosed in U.S. Patent No. 9,001,047 (RX-0673, "Apple '047), and Dr. Warren testified that it would have been obvious to incorporate such a touch-screen with the display of a blood oxygen measurement disclosed in Lumidigm. Tr. (Warren) at 1240:4-1242:9. Apple also identifies certain references to "touch buttons" in Webster. RIB at 133 (citing RX-0035 at 114, 137, 218-223).

Complainants argue that Lumidigm provides no clear disclosure of a touch-screen in combination with its wristwatch embodiment and/or the extended functionality for measuring physiological parameters. CIB at 141-42; CRB at 51. With respect to Apple '047, Complainants argue that there is no disclosure of a user-worn device or any display of a physiological parameter such as an oxygen saturation measurement. CIB at 156-57; see Tr. (Madisetti) at 1337:3-11. Complainants argue that Apple has failed to show any motivation to combine or likelihood of success in adding a touch-screen to the wristwatch embodiment in Lumidigm. CIB at 157; CRB at 84-85.

In consideration of the parties' arguments, the undersigned agrees with Complainants that Lumidigm fails to disclose a touch-screen user interface for display of an oxygen saturation measurement in conjunction with the wristwatch embodiment, and Apple has not clearly and convincingly shown that this addition would be obvious. Dr. Warren's testimony on this issue is

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conclusory. *See* Tr. (Warren) at 1226:22-1227:7, 1240:4-17, 1241:1-17; RDX-8.83-84. Apple relies on Lumidigm's identification of certain portable electronic devices with screens, but with no reference to touch-screen input. *See* RIB at 131 (citing RX-0411 Figs. 8B-8E, 3:35-37, 21:29-36). Moreover, the cellular phone and PDA embodiments are identified as separate from the wristwatch embodiment, with no suggestion that parts of these different portable electronic devices should be combined. *See id.* at 10:42-13:26. Lumidigm's wristwatch embodiment is depicted as an analog clock face with no screen for displaying any measurement. *See id.* at 11:60-12:2, Fig. 8B. ⁵²

The undersigned further finds that Apple has not clearly and convincingly identified a reason one of ordinary skill would have combined Lumidigm's wristwatch with the touch-screen interface disclosed in Apple '047 and shown that such a combination would have had a reasonable expectation of success. Dr. Warren's testimony on these issues is conclusory and fails to offer any reason for adding a touch-screen to Lumidigm's wristwatch—he merely offers his opinion that a touch-screen "is a well-known mechanism" and that "a person of ordinary skill would realize that, to add the features of . . . [a] touchscreen to Lumidigm, they could look to a number of references, but . . . Apple would be an obvious choice." Tr. (Warren) at 1240:4-1242:9. With respect to this limitation, Dr. Warren appears to have relied on the "touch-screen display" in the claim language as his only reason for incorporating this feature, and the Federal Circuit has held that such an approach is inadequate to prove obviousness. *See InTouch Techs.*, *Inc. v. VGO Commc'ns, Inc.*, 751 F.3d 1327, 1352 (Fed. Cir. 2014) (reversing jury's finding of

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⁵² As discussed above regarding Element [28J], Lumidigm discloses a network interface for wirelessly communicating the measurement of a physiological parameter from the wristwatch to an external device (where it can be read). *See* Element [28J] *supra*; RX-0411 at 11:38-55; RIB at 94-95.

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obviousness where expert used the asserted patent as a "roadmap" and her "testimony primarily consisted of conclusory references to her belief that one of ordinary skill in the art could combine these references, not that they would have been motivated to do so.").

Apple '047 also fails to disclose any use of a touch-screen in a wristwatch—it is primarily directed to "a rectangular touch screen display with a portrait view and a landscape view." See RX-0673 at 2:53-3:57 (describing embodiments of rectangular touch screen displays), Fig. 2; see Tr. (Warren) at 1240:18-25 (describing Apple '047). Apple's prior art touch-screen does not appear to be compatible with the wristwatch disclosed in Lumidigm, which has an analog clock face with a circular shape, and Dr. Warren did not provide testimony addressing this issue. See RX-0411 at Fig. 8B. Moreover, to the extent that Apple relies on Webster, Apple has not shown that any of the displays or user interfaces identified in Webster are touch-screens. See RX-0035 at 114, 137, 218-223.⁵³

m. Element [28L]: "a storage device configured to at least temporarily store at least the measurement"

With respect to the "storage device" limitation, Apple identifies Lumidigm's disclosure of computer hardware elements in Figure 9, including storage device 338, memory 348, and computer-readable storage medium 340b. RX-0411 at 12:63-13:9. Lumidigm provides that "[t]he storage devices typically hold information defining the stored spectra as well as any personalized-setting information that may be used." *Id.* at 13:12-14. Complainants dispute this limitation, arguing that there is no clear disclosure of the storage devices in Figure 9 in

⁵³ Complainants argue that Apple failed to cite Webster with respect to this limitation in its pre-hearing brief. *See* CRB at 84. The undersigned agrees with Complainants that this contention is untimely, but even if these disclosures in Webster were considered, it would not change the determination regarding obviousness.

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combination with the wristwatch embodiment and/or the extended functionality for measuring physiological parameters. CIB at 141-42; CRB at 51.

In consideration of the parties' arguments, the undersigned finds that Lumidigm discloses a storage device configured to store measurements from its biometric sensor. As discussed above in the context of the "one or more processors" limitation of '501 patent claim 1, Lumidigm explicitly notes that some of the components in Figure 9 could be used in portable devices, which includes the "wristwatch" embodiment. RX-0411 at 13:21-37 (identifying a "second set of embodiments" involving "a portable electronic device having extended functionality," and including "a cellular telephone, a personal digital assistant, an electronic fob, and a watch" as examples of the "electronic arrangement"), 2:58-61, 17:67-18:2. Lumidigm explicitly provides that "[t]he storage devices typically hold information defining the stored spectra," and the blood oxygen measurement described in Lumidigm is defined by "spectroscopic changes" that are "correlated with oxygenation." Id. at 13:12-14, 19:24-26. Accordingly, the "storage device" limitation of '502 patent claim 28 is disclosed in Lumidigm, except to the extent that this limitation requires storage of an oxygen saturation measurement.

> Element [28M]: "a strap configured to position the user-worn device on the user"

With respect to the "strap" limitation, Apple identifies the strap depicted in Lumidigm's "wristwatch" embodiment. See RX-0411 at 11:60-64, Fig. 8B. There is no dispute that Lumidigm meets the "strap" limitation of '502 patent claim 28.

* * *

For the reasons discussed above, the evidence fails to clearly and convincingly disclose a combination of elements meeting the limitations of claim 28 of the '502 patent, and Apple has

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not shown a reasonable expectation of success in achieving a combination of these elements in Lumidigm's wristwatch embodiment.

'648 Patent Claim 12

As discussed below, the evidence fails to clearly and convincingly show that claim 12 is obvious in view of Lumidigm alone or in combination with other asserted prior art.

> Element [8 preamble]: "A user-worn device configured to nona. invasively determine measurements of a physiological parameter of a user, the user-worn device comprising:"

For the same reasons discussed above in the context of the preamble limitations of '501 patent claim 1 (Element 1[A]), Lumidigm meets the preamble limitations of '648 patent claim 8 requiring a "user-worn device configured to non-invasively determine measurements of a physiological parameter of a user."

> b. Element [8A]: "a first set of light emitting diodes (LEDs), the first set comprising at least an LED configured to emit light at a first wavelength and at least an LED configured to emit light at a second wavelength"

For the same reasons discussed above in the context of Element [28A] of the '502 patent, the evidence shows that this limitation is met by Lumidigm.

> Element [8B]: "a second set of LEDs spaced apart from the C. first set of LEDs, the second set of LEDs comprising an LED configured to emit light at the first wavelength and an LED configured to emit light at the second wavelength"

For the same reasons discussed above in the context of Element [28B] of the '502 patent, the evidence shows that this limitation is met by Lumidigm.

Element [8C]: "four photodiodes" d.

For the same reasons discussed above in the context of the "four photodiodes" limitations of 502 patent claim 19 (Element [19B]), the undersigned finds that the "four photodiodes" limitation of '648 patent claim 8 is met by Lumidigm.

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e. Element [8D]: "a protrusion comprising a convex surface, at least a portion of the protrusion comprising an opaque material"

For the same reasons discussed above in the context of the "protrusion" and "opaque lateral surface" limitations of '501 patent claim 1 (Elements [1C], [1D], and [1E]), the evidence shows that Lumidigm, in view of the prior art, provides a reason to modify the optical surface to form a "protrusion comprising a convex surface" with a portion of the protrusion (the openings) comprising an opaque material.

f. Element [8E] and Element [8F]: "a plurality of openings provided through the protrusion and the convex surface, the openings aligned with the photodiodes" and "a separate optically transparent window extending across each of the openings"

For the same reasons discussed above in the context of the "plurality of openings" limitations of '502 patent claim 19 (Element [19C]), the evidence fails to show, clearly and convincingly, a "plurality of openings" with a "separate optically transparent window extending across each of the openings" in combination with the "four photodiodes" embodiments of Lumidigm relied upon by Apple. *See* RIB at 82, 91, 98.

g. Element [8G]: "one or more processors configured to receive one or more signals from at least one of the photodiodes and output measurements of a physiological parameter of a user"

For the same reasons discussed above in the context of the "one or more processors" limitation of '501 patent claim 1 (Element [1F]), the undersigned finds that the "one or more processors" limitation of '648 patent claim 8 is met by Lumidigm.

h. Element [8H]: "a housing"

With respect to the "housing" limitation, Apple identifies Lumidigm's disclosure that "the biometric reader 111 is built in the case of a wristwatch 112." RX-0411 at 11:60-64, Fig.

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8B. There is no dispute that Lumidigm thus discloses a housing in its "wristwatch" embodiment.

The evidence shows that this limitation is met by Lumidigm.

i. Element [8I]: "a strap configured to position the housing proximate tissue of the user when the device is worn"

For the same reasons discussed above in the context of the "strap" limitation of '502 patent claim 28 (Element [28M]), the evidence shows that the "strap" limitation of '648 patent claim 8 is met by Lumidigm.

j. Element [12]: "wherein the physiological parameter comprises oxygen or oxygen saturation"

'648 patent claim 12 depends from claim 8 and further requires that "the physiological parameter comprises oxygen or oxygen saturation." For the same reasons discussed above in the context of the preamble limitations of '502 patent claim 19, this limitation is not met by Lumidigm, because the evidence shows that one of ordinary skill would not have been able to successfully configure Lumidigm's wristwatch to measure blood oxygen.

5. '648 Patent Claim 24

As discussed below, the evidence fails to clearly and convincingly show that claim 24 of the '648 patent is rendered obvious by Lumidigm alone or in combination with other prior art.

a. Element [20 preamble]: "A user-worn device configured to non-invasively determine measurements of a user's tissue, the user-worn device comprising:"

Complainants dispute this limitation on the grounds that Lumidigm does not disclose measurement of a "physiological parameter" (see CIB at 124-125). For the same reasons discussed above in the context of the preamble limitations of '501 patent claim 1, Lumidigm discloses the preamble limitations of '648 patent claim 20 requiring a "user-worn device configured to non-invasively determine measurements of a user's tissue." Moreover, the preamble language of Element [20 preamble] does not necessarily require measurement of a

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"physiological parameter," only "measurements of a user's tissue." Lumidigm clearly shows that the biometric functionality of the wristwatch embodiment requires "measurements of a user's tissue," and Complainants do not dispute that the wristwatch embodiment of Lumidigm performs biometric functionality. See RX-0411 at 5:30-44 (describing biometric identification of an individual based on comparing "tissue spectral data taken at the time of use and compared to stored tissue spectral data from prior measurement") (emphasis added); CIB at 125 (describing Lumidigm's wristwatch as "identifying a user or authorizing them to do something using 'tissue spectral data'").

b. Element [20A]: "a plurality of light emitting diodes (LEDs)"

For the same reasons discussed above in the context of Element [1A] of the '501 patent claim 1, this limitation is met by Lumidigm.

c. Element [20B]: "at least four photodiodes configured to receive light emitted by the LEDs, the four photodiodes being arranged to capture light at different quadrants of tissue of a user"

For the same reasons discussed above in the context of Element [28C] of the '502 patent, the evidence shows that this limitation is met by Lumidigm.

d. Element [20C]: "a protrusion comprising a convex surface"

For the same reasons discussed above in the context of the "protrusion" limitation of '501 patent claim 1 (Element [1C]), the evidence clearly and convincingly shows that Lumidigm's disclosures, in view of the prior art, provide a reason to modify Lumidigm's "optical surface" to form a protrusion comprising a convex surface, and a reasonable expectation of success in doing so.

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e. Element [20D]: "and a plurality of through holes, each through hole including a window and arranged over a different one of the at least four photodiodes"

For the same reasons discussed above in the context of Element [19C] of the '502 patent, the evidence is insufficient to show, clearly and convincingly, that the prior renders obvious a protrusion comprising a plurality of through holes where each through hole is "arranged over a different one of the at least four photodiodes," in combination with all other elements of this claim.

f. Element [20E]: "one or more processors configured to receive one or more signals from at least one of the photodiodes and determine measurements of oxygen saturation of the user"

For the same reasons discussed above in the context of the preamble of '502 patent claim 19, the undersigned finds that the "one or more processors" limitation of '648 patent claim 20 is not met by Lumidigm, because one of ordinary skill would not have been able, without undue experimentation, to configure Lumidigm's wristwatch to determine measurements of oxygen saturation.

g. Element [24]: "wherein the protrusion comprises opaque material configured to substantially prevent light piping"

Claim 24 of the '648 patent depends from claim 20, further requiring that "the protrusion comprises opaque material configured to substantially prevent light piping." For the same reasons discussed above in the context of the "opaque lateral surface" limitation of '501 patent claim 1 (Element [1E]), the undersigned finds that "opaque material configured to substantially prevent light piping" is disclosed by Lumidigm, but not in combination with all the other elements of claim 20.

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6. '648 Patent Claim 30

Claim 30 of the '648 patent depends from claim 20, further requiring that "the protrusion further comprises one or more chamfered edges." Apple contends that chamfered edges were well-known in the art. See Tr. (Warren) at 1228:24-1229:10. Apple further submits that chamfered edges are depicted in Seiko 131 and in Cramer. See RX-0666 at Fig. 5; RX-0670 at Fig. 3; Tr. (Warren) at 1236:3-16. Dr. Warren explained that such features would be implemented for comfort, in accordance with Lumidigm's teaching that modifications to the sensor surface could be made "to incorporate ergonomic features." Tr. (Warren) at 1228:24-1229:10 (quoting RX-0411 at 7:57-63). Dr. Warren further testified that "a person of ordinary skill would understand that chamfered edges have been around for many decades as a means to soften transitions between surfaces and make items such as watches more wearable." Id. at 1236:17-1237:3.

Complainants argue that Lumidigm fails to disclose or suggest a chamfered edge. CIB at 142-43. Complainants argue that the chamfered edges disclosed in Cramer are not on the alleged protrusions. *Id.* at 147. Similarly, Complainants argue that the chamfered edges disclosed in Seiko 131 are not on the alleged protrusion. *Id.* at 150. Complainants argue that Apple has failed to show why a person of ordinary skill would have been motivated to use a chamfered edge in Lumidigm's wristwatch embodiment with a reasonable expectation of success. CRB at 76-78.

In consideration of the parties' arguments, the evidence shows that chamfered edges were known in the prior art, and one of ordinary skill in the art would have reason to implement a chamfered edge on the sensor surface of Lumidigm's wristwatch for ergonomic reasons with a reasonable expectation of success. The record contains numerous examples of chamfered edges

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in the prior art, including on the front face of Lumidigm's wristwatch and on the back face of Cramer's wristwatch. *See* RX-0411 at Fig. 8B; RX-0670 at Fig. 3.⁵⁴ This is clear evidence that chamfered edges were used in wristwatches and would have been known to persons of ordinary skill in the art. *See* Tr. (Warren) at 1228:24-1229:10, 1236:17-1237:3. Lumidigm provides an express motivation to modify the curvature of its sensor surface "to incorporate ergonomic features that allow for good optical and mechanical coupling with the tissue being measured, or for other technical or stylistic reasons." RX-0411 at 7:58-63.

Although the prior art provides a reason to incorporate a chamfered edge into a protrusion on the back face of a wristwatch, with a reasonable expectation of success, the evidence fails to show that this limitation in combination with the other limitations of claim 30 (including all limitations of independent claim 20) are rendered obvious. Accordingly, Apple has not shown that claim 30 of the '648 patent is invalid for obviousness.

7. Objective Indicia of Non-Obviousness

Complainants contend that the asserted claims of the Poeze patents are not obvious in view of certain objective indicia of non-obviousness, including skepticism and failure of others, unexpected results, copying, and commercial success. CIB at 158-75; CRB at 85-96. For the

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⁵⁴ Complainants argue that the chamfered edges in Cramer are not on the alleged convex portions of the protrusion, CIB at 147, but claim 30 does not require the chamfered edge and the convex surface to be on the same part of the protrusion—the claim language recites "a protrusion comprising a convex surface," and "wherein the protrusion further comprises one or more chamfered edges." *See* '648 patent claim 20, claim 30.

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reasons set forth below, the evidence regarding the objective indicia of non-obviousness do not weigh significantly against an obviousness finding.

a. Skepticism and Unexpected Results for Convex Protrusions

Complainants contend that there was skepticism in the industry for convex protrusions, citing evidence from Apple's development of the Apple Watch wherein Apple engineers identified

. See CX-1789C; CX-1790C.	
CX-0114C at 2-3. An Apple patent application	
filed in July 2016 described benefits of a convex protrusion: "A convex shape can enable	
improved contact with the user's skin and can be more comfortable for the user than other	
shapes." CX-1569 at 9:35-37. Another Apple patent filed in May 2016 described a protrusion	

"configured to create pressure to skin." CX-1806 at ¶ [0033]. "By applying localized pressure to the individual's skin, the pressure gradient across arterial walls can be reduced, which can lead to an increase in pulsatile (AC) signal." *Id.* at ¶ [0032].

Complainants also contend that the results of a convex protrusion were unexpected within Cercacor. See CIB at 162. Mr. Kiani testified that Cercacor engineers were surprised that they achieved a stronger signal when trying to measure hemoglobin and glucose levels using a protrusion that applied pressure to a finger. Tr. (Kiani) at 98:9-99:16. Complainants argue that this result conflicts with a prior art patent, U.S. Patent No. 6,801,799 (CX-1733, "Mendelson"), which warned against pressure on the skin during pulse oximetry measurements. See CX-1733 at 2:47-57 ("[V]ariations in contact pressure between the sensor and the skin can cause large

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errors in reflection pulse oximetry (as compared to transmission pulse oximetry) since some of the blood near the superficial layers of the skin may be normally displaced away from the senor housing towards deeper subcutaneous structures."); see Tr. (Madisetti) at 1374:9-12. Complainants also cite the testimony of Robert Rowe, one of the Lumidigm inventors, who described a shape that matches the skin, e.g., a concave shape to match a cylindrical body part, as a way to achieve "good coupling." RX-0279C (Rowe Dep. Tr.) at 69:8-21.

Apple disputes Complainants' interpretation of Apple's engineering documents, asserting

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concave shape. Id. With respect to the Apple patent applications describing convex protrusion, Apple argues that these features were not individually claimed to be novel. Id. at 68.

In reply, Complainants argue that Mendelson teaches the undesirability of displacing blood away from the sensor, which would be caused by a convex protrusion. CRB at 91. Complainants contend that Nippon fails to disclose a convex protrusion and was considering during the prosecution of the Poeze patents. *Id.* at 91-92. Complainants submit that Mr. Rowe's testimony is consistent with the teachings in Mendelson and that Mr. Kiani's testimony regarding the surprising benefits of a convex protrusion is consistent with the advantages described in Apple's patent applications. *Id.* at 92-94.

In consideration of the parties' arguments, the evidence does not show that there was skepticism in the industry regarding convex surfaces. As discussed above in the context of the "protrusion" limitation of '501 patent claim 1, there is no evidence in the prior art that convex surfaces were disfavored before the invention of the Poeze patents. The parties have identified prior art physiological sensors with concave, convex, and flat surfaces, which is convincing evidence that the shape of the sensor surface was a design choice for persons of ordinary skill in the art "to match the profile of a device in which it is mounted, to incorporate ergonomic features that allow for good optical and mechanical coupling with the tissue being measured, or for other technical or stylistic reasons." RX-0411 at 7:57-63; see also RX-0666 at 3:22-28, Fig. 28; RX-0670 at 5:45-51, Fig. 3; RX-0665 at 5:12-17, Fig. 3b. The Apple engineering documents that Complainants cite to show alleged skepticism are not clearly directed to the accused convex protrusions, and the undersigned agrees with Apple that this evidence should be discounted in view of the evidence that the back surface of the Apple Watch had a convex shape even before the pulse oximetry feature was implemented. See RRB at 66-67.

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In addition, the undersigned finds that Complainants have not shown that a gain in signal strength with convex surfaces was an unexpected result that demonstrates non-obviousness.

Complainants have identified evidence that both Cercacor engineers and Apple engineers were

but the evidence in the prior art is mixed on the question of whether this result should have been unexpected. Compare CX-1733 at 2:47-57 (describing "large errors" caused by "variations in contact pressure") to RX-0665 at 5:12-17 (recognizing that a detector that "protrudes into the tissue slightly" has the effect of "increasing the signal strength of the detected signal."). 55 Moreover, to the extent that an improvement in signal strength is attributable to the increased pressure caused by a convex protrusion, the record shows that this effect was recognized in the prior art: Seiko 131 identifies a convex surface that improves "positive contact between the body surface and outside surface of the light transmittance plate." RX-0666 at 3:22-28, Fig. 28.; and Nippon describes increased signal strength from a protrusion into the tissue. RX-0665 at 5:12-17, Fig. 3b. The Federal Circuit has discounted evidence of unexpected results when the result was produced by a feature known in the prior art. Kennametal, Inc. v. Ingersoll Cutting Tool Co., 780 F.3d 1376, 1385 (Fed. Cir. 2015) ("[T]he offered secondary consideration actually results from something other than what is both claimed and novel in the claim, so there is no nexus to the merits of the claimed invention." (citing In re Huai-Hung Kao, 639 F.3d 1057, 1068 (Fed. Cir. 2011) (internal quotations removed)).

⁵⁵ In the pulse oximeter described in the specification of the Poeze patents, the benefits of a convex protrusion are attributed to the reduced thickness of the finger—not the pressure on the skin. *See* JX-0001 at 21:9-34 (describing signal gain in the context of the Beer Lambert law, which relates transmittance to the path length traveled by the light: "In an embodiment where the protrusion 305 is a convex bump, the thickness of the finger can be reduced to 10 mm (from 12 mm) for some fingers and the effective light mean path is reduced to about 16.6 mm from 20 mm.").

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b. Skepticism and Failures Measuring Pulse Oximetry at the Wrist

Complainants fu	irther cite evidence that the
in the	Apple Watch is evidence that measuring pulse oximetry at the wrist
would have been non-ol	bvious. CIB at 165-72; CRB at 85-88. Complainants identify evidence
that Apple	
	. See CX-
1793C (). Paul Mannheimer was hired to be Apple's sensor architect
in 2014, and he express	ed skepticism that pulse oximetry could be successfully implemented in a
wristwatch. Tr. (Mannl	heimer) at 996:25-997:5. Stephen Waydo, the director of Apple's team
for health algorithms, al	lso expressed skepticism that blood oxygen could be measured on the
wrist, calling the develo	opment this feature "extremely challenging." Tr. (Waydo) at 938:21-24.
This skepticism was sha	ared by other Apple engineers. See CX-0295C (Shui Dep. Tr.) at 108:13-
21; CX-0283C (Lefort)	at 198:8-199:2. Apple did not implement a blood oxygen feature in any
of the first six Apple W	atches that were commercially released from 2015 to 2019. Tr.
(Mannheimer) at 1013:	7-20.
	CX-
0177C at 13; see Tr. (M	Jannheimer) at 1015:9-19; Tr. (Land) at 982:3-983:12. Apple engineers
filed for a patent on a se	ensor window design for the Apple Watch in July 2016, which issued as
U.S. Patent No. 10,702,	211 in July 2020. CX-1569. The first Apple Watch with a pulse
oximetry feature was re	leased in September 2020: the Apple Watch Series. RX-0333.
Apple argues tha	at the skepticism of its engineers regarding the implementation of pulse
oximetry in the Apple V	Vatch was related to "
	" RRB at 52-53 Dr. Warren cited

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evidence that his own students had built pulse oximeters that could take measurements at the wrist as early as 2002. Tr. (Warren) at 1216:10-25; RX-0632; RX-0504; RX-0508. Apple further argues that the evidence regarding the Apple Watch is irrelevant, because the Poeze Patents provide no teachings for measuring blood oxygen on the wrist. RRB at 68.

In consideration of the parties' arguments, the undersigned finds that the skepticism of Apple engineers regarding pulse oximetry at the wrist (and discussed in Part IV.G.2.a supra) is consistent with the finding *supra* that Lumidigm's wristwatch embodiment, as modified in view of the combinations Apple proposes, does not disclose or render obvious a device for measuring blood oxygenation at the wrist. However, while this evidence is highly relevant to the obviousness determination for the reasons discussed in Parts IV.G.2-6 above, ⁵⁶ this evidence does not weigh significantly in terms of objective indicia of non-obviousness because the asserted claims apply to any "user-worn device," including user-worn devices that are not on the wrist. See Therasense Inc. v. Becton Dickinson and Co., 593 F.3d 1325, 1336 (Fed. Cir. 2010) (objective evidence of non-obviousness should be "commensurate in scope with the claims which the evidence is offered to support"); id. (evidence of long-felt but unsolved need to solve "short fill" problem did not weigh against obviousness finding where the claims "are not limited to sensors that prevent short fill"); 501 patent at 11:45-48 ("In some embodiments, the measurement site 102 is located somewhere along a non-dominant arm or a non-dominant hand, e.g., a right-handed person's left arm or left hand."); id. at 8:21-23 (discussing "measurement sites, including, for example, a finger, toe, hand, foot, ear, forehead, or the like"); id. at 10:22-24

⁵⁶ As discussed *supra*, Apple's obviousness arguments rely on the wristwatch embodiment of Lumidigm as the primary reference.

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("[m]any of the foregoing arrangements allow the sensor to be attached to the measurement site while the device is attached elsewhere on the patient, such as the patient's arm"). 57

c. Apple's Alleged Copying of Masimo Technology

Complainants further allege that Apple copied Masimo's patented technology in its development of the pulse oximetry feature in the Apple Watch. CIB at 172-73; CRB at 94-96. Complainants cite testimony and evidence showing that Apple See Tr. (Waydo) at 945:10-946:6; CX-0125C; CX-0126C. Beginning in 2013, Apple met with Masimo employees See CX-1793C); CX-0185C at 20 (); Tr. (Kiani) at 104:14-22, 107:1-108:18. Apple hired several Masimo employees, including Masimo's Chief Medical Officer, Michael O'Reilly, and one of the named inventors of the Poeze patents, Steve Lamego. See Tr. (Kiani) at 110:23-111:23; CX-1615C. Complainants allege that Apple sought to obtain Masimo's technology by hiring Dr. Mannheimer from Nellcor, a Masimo competitor that was found to have infringed Masimo's patents in 2004. CIB at 168-69. Complainants submit that Apple has provided no credible explanation for the convex shape of the back crystal in the design of the Apple Watch and argue that an inference of copying is appropriate. CRB at 95. Complainants cite evidence that . See CX-0285C (Dua Dep. Tr.) at 105:22-107:9; CX-0096C. Complainants further submit that

⁵⁷ In addition, the asserted claim of the '501 patent is not limited to devices that perform pulse oximetry.

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See Tr. (Waydo) at 932:19-933:4; CX-0127C; CX-0097C at 3; CX-0094C.

Apple argues that the pulse oximetry features of the Apple Watch could not have been copied from the Poeze patent claims, because the applications reciting these claims were not filed until after the Apple Watch Series 6 had been released. RIB at 140. Apple further argues that it could not have copied the patented features from any Masimo product, because the first Masimo product embodying the asserted claims was not released to the public until January 2022—during discovery in this investigation. Id. Apple's engineers have consistently testified that they did not copy Masimo or any other company's technology. *Id.* at 140-41 (citing Tr. (Block) at 902:10-12, 914:1-7; Tr. (Waydo) at 932:6-9, 933:8-11; Tr. (Land) at 972:19-22, 991:23-25; Tr. (Venugopal) at 833:13-17; Tr. (Mehra) at 893:15-17; Tr. (Mannheimer) at 1007:22-1008:7; CX-0283C (Charbonneau-Lefort Dep. Tr.) at 171:21-173:8, 201:10-19; CX-0285C (Dua Dep.) at 160:20-161:5). Apple contends that was not related to the development of the pulse oximetry feature for the Apple Watch and argues that there is no evidence that this product practices any asserted claim. RIB at 142.

. *Id.* at 143; RRB at 70 (citing Tr. (Diab) at 243:9-17; Tr. (Scruggs) at 446:8-23). Apple submits that none of the employees hired from Masimo contributed to the design of the pulse oximetry feature in the Apple Watch. RIB at 142-43. (citing Tr. (Land) at 972:23-973:3, Tr. (Waydo) at 950:1-15; Tr. (Venogupal) at 833:14-17. Apple explains that

during the development of the Apple Watch to avoid the disclosure of information regarding an "unreleased feature." CX-0285C (Dua Dep. Tr.) at

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105:22-107:9. With respect to Dr. Waydo's discussion of

, Apple submits that this was related to the problem of taking measurements during motion, which was not implemented in the Apple Watch. CX-0299C (Waymo Dep. Tr.) at 173:3-174:8; Tr. (Waydo) at 932:6-18.

In consideration of the parties' arguments, the undersigned finds no significant credible evidence that Apple copied Masimo's patented technology. Complainants accuse numerous former Masimo employees of copying Masimo's technology but fails to identify the patented features that were allegedly copied. Complainants' theory that Apple's hiring of Dr. Mannheimer from Nellcor was motivated by a desire to copy Masimo's technology lacks evidentiary support. The allegation that Apple copied the convex shape of the Apple Watch's back crystal from Masimo is purely speculative, and as discussed above, such convex surfaces were known in the prior art. Complainants fail to identify which features of the pulse oximeters used as benchmarks were allegedly copied by Apple, and there is no evidence that any of these products practices asserted claims of the Poeze patents. Complainants' allegations are insufficient to demonstrate copying. See Iron Grip Barbell Co., Inc. v. USA Sports, Inc., 392 F.3d 1317, 1325 (Fed. Cir. 2004) ("Not every competing product that arguably falls within the scope of a patent is evidence of copying.

patents. Complainants' allegations are insufficient to demonstrate copying. See Iron Grip

Barbell Co., Inc. v. USA Sports, Inc., 392 F.3d 1317, 1325 (Fed. Cir. 2004) ("Not every
competing product that arguably falls within the scope of a patent is evidence of copying.

Otherwise every infringement suit would automatically confirm the nonobviousness of the
patent."); see also Wyers v. Master Lock Co., 616 F.3d 1231, 1246 (Fed. Cir. 2010) ("Our case
law holds that copying requires evidence of efforts to replicate a specific product, which may be
demonstrated through internal company documents, direct evidence such as disassembling a
patented prototype, photographing its features, and using the photograph as a blueprint to build a

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replica, or access to the patented product combined with substantial similarity to the patented product.").

d. **Commercial Success of Apple Watch Products**

Complainants allege that the commercial success of the Apple Watch Series 6 and 7 products is objective evidence of non-obviousness. CIB at 173-75; CRB at 95-96. According to Complainants' expert Daniel McGavock, sales of the Apple Watch Series 6 far exceeded the sales of previous Apple Watches, and Apple advertised the blood oxygen feature as the key differentiator of the Series 6 over the Series 5. Tr. (McGavock) at 1416:10-21, 1422:8-1425:13: CX-0252; CX-1451; CX-1532; CX-1289. Mr. McGavock referenced third party reviews identifying the blood oxygen feature as the key feature for the Apple Watch Series 6. Tr. (McGavock) at 1418:21-1419:8 (citing CX-1634; CX-1301). Dr. Madisetti agreed with Mr. McGavock that there was a nexus between the blood oxygen feature of Apple Watch Series 6 and its commercial success. Tr. (Madisetti) at 1380:14-1381:4.

Apple argues that the commercial success of the Apple Watch Series 6 and 7 is attributable to many features. RIB at 144; RRB at 71; see Tr. (Warren) at 1242:16-25; Tr. (Land) at 970:10-971:6. According to Deidre Caldbeck, Apple's Director of Product Marketing for the Apple Watch, pulse oximetry is "not even in the top 30 use apps on Apple Watch." CX-0275 (Caldbeck Dep. Tr.) at 65:21-22, 66:3-12. Apple argues that its marketing materials describe many different features of the Apple Watch Series 6 in addition to pulse oximetry. See, e.g., CX-1447; CX-0252; CX-1532; CX-1451. Apple further points out that Mr. McGavock cited certain third-party reviews of the Apple Watch that criticized the pulse oximetry feature of the Apple Watch Series 6. See Tr. (McGavock) at 550:20-551:17 (citing CX-1616; CX-1293; CX-1409).

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In consideration of the parties' arguments and the record evidence, the undersigned finds that the Apple Watch Series 6 was commercially successful and that this may be due in some part to its blood oxygen monitoring features. There is no dispute that the Apple Watch Series 6 was commercially successful. *See* Tr. (McGavock) at 1419:9-1420:1; CX-1285 (*AppleInsider*: "Apple Watch far outsold all other smartwatches in Q4 2020"). Apple's marketing materials upon introduction of the Apple Watch Series 6, as well as certain third-party reviewers, identified the measurement of blood oxygen as a key new feature. *See, e.g.*, CX-0252; CX-1289; CX-1451; CX-1301 (*New York Times*: "The new Apple Watch can be summed up in two words: blood oxygen."); CX-1643 (*Independent*: "it's the blood oxygen sensor that dominated the introduction, and which is the new feature that Apple has spent the most time talking about.").

The evidence does not persuasively indicate, however, that the sales of the Apple Watch Series 6 are largely attributable to the blood oxygen feature, as market analysts have recognized the Apple Watch's "blend of sleek design, good usability on a small screen, and a growing portfolio of health and fitness apps." CX-1644 (Strategy Analytics). Moreover, it is not clear that the Apple Watch Series 6 was significantly more successful than other smartwatches, because the growth in Apple's smartwatch sales from 2020 to 2021 is in line with the growth of smartwatch sales across the industry. *See id.* (Apple's growth in smartwatch sales is 46%, and the overall industry growth in smartwatch sales is 47%). This evidence shows that much of the success of the Apple Watch Series 6 can be attributed to the growing market for smartwatches rather than the specific implementation of the pulse oximetry feature claimed in the patents-at issue. *See id.* ("Online sales of fitness-led devices that help to support personal healthcare remain popular and are the main driver of the smartwatch boom."); *see also* CX-0275 (Caldbeck Dep.) at 65:21-22, 66:3-12 (blood oxygen app in Apple Watch is "not even in the top 30 used

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apps on Apple Watch"). The Federal Circuit has discounted evidence of commercial success in such circumstances, where "the evidence does not show that the commercial success was the result of claimed and novel features." *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1313 (Fed. Cir. 2006) (recognizing that the commercial success was due in part to "aesthetic appeal and improved comfort" and features that were known in the prior art).

The undersigned thus finds that there is little evidence of a significant nexus between Apple's commercial success and the allegedly nonobvious features of the asserted Poeze patent claims, particularly for claim 12 of the '501 patent (which is not limited to blood oxygen measurements). Accordingly, this commercial success does not meaningfully affect the obviousness analysis discussed above.

H. Invalidity - Written Description and Enablement

Apple contends that the asserted claims of the Poeze patents are invalid for lack of written description and/or enablement pursuant to 35 U.S.C. § 112, relying on the testimony of Dr. Warren. RIB at 147-53; RRB at 73-76; Tr. (Warren) at 1246:24-1248:4. Complainants dispute Apple's allegations, identifying support in the specification of the Poeze patents and relying on the testimony Dr. Madisetti. CIB at 175-83; CRB at 100-105; Tr. (Madisetti) at 1347:14-1353:25. For the reasons discussed below, the evidence shows, clearly and convincingly, that '502 patent claim 28 and '648 patent claim 12 are invalid for lack of written description. The evidence does not show, clearly and convincingly, that the other asserted claims are invalid for lack of written description and/or lack of enablement.

Combination of LEDs, Photodiodes, and Openings (All Asserted Claims)

Apple argues that all of the asserted claims of the Poeze patents are invalid for lack of written description because the specification fails to disclose an embodiment that includes "(a)

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multiple LEDs, (b) multiple photodiodes, and (c) a protrusion with a plurality of openings, positioned or arranged over the photodiodes, each of which includes an opaque lateral surface or is lined with an opaque material." RIB at 148. Apple further argues that the specification fails to disclose sets of three or more LEDs or three or more photodiodes. *Id.* at 147-51; RRB at 73-75; *see* Tr. (Warren) at 1246:24-1247:7

Complainants identify Fig. 7B of the Poeze patents, which depicts two emitters 104, two photodiodes 106, one or more opening(s) 703, a protrusion 705b that is a "convex bump," and a shielding enclosure 790. JX-001 at 27:13-41.

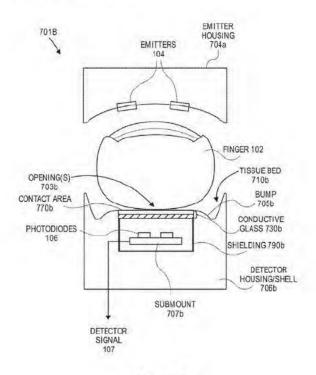
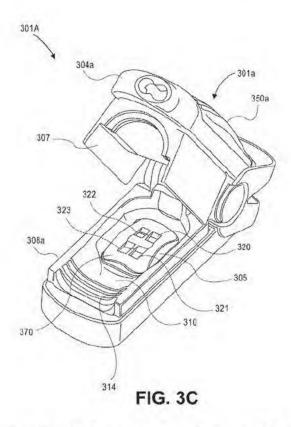


FIG. 7B

Id. at Fig. 7B. Figure 7B depicts two emitters and two detectors. *Id.* There are "one or more openings 703b," and "each of the openings 703 can include a separate window of the conductive glass 703b." *Id.* at 27:18-24. The specification provides that "shielding enclosure 790b... can have all the features of the shielding enclosure 790a." *Id.* at 27:28-29. "The shielding or

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enclosure a can include an opaque material to not only reduce electrical noise, but also ambient optical noise." *Id.* at 27:1-3. The specification expressly provides that the sensors 701 depicted in Figure 7A and 7B "can be implemented with any of the sensors 101, 201, 301 described above." *Id.* at 26:25-26. One embodiment of sensor 301 is depicted in Figure 3C, which shows four photodetectors in four separate openings. *Id.* at 19:38-48.



Id. at Fig. 3C. Complainants cite a disclosure from another part of the specification describing a "system 100 that comprised four LEDs in emitter 104 and four independent detector streams from detectors 106." Id. at 44:22-29, Fig. 21. Moreover, in Figure 13, "n emitters and n detectors are shown," although "the number of emitters and detectors need not be the same in certain implementations." Id. at 33:37-39, Fig. 13. Dr. Madisetti testified that these disclosures

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provide full written description support for multiple LEDs, three or more photodiodes, and opaque lateral surfaces. Tr. (Madisetti) at 1347:18-1349:6.

In consideration of the parties' arguments, the evidence fails to show, clearly and convincingly, that the asserted claims reciting three or more LEDs, three or more photodiodes, and a protrusion with a plurality of openings over the photodiodes with opaque lateral surfaces lack written description. The specification of the Poeze patents expressly states that Figure 3C and Figure 7B are not distinct embodiments—"[t]he features of the sensors 701 can be implemented with any of the sensors 101, 201, 301 described above. JX-001 at 26:25-26. Figure 3C clearly depicts four photodiodes in separate openings. *Id.* at 19:38-48, Fig. 3C. Figure 7B clearly depicts these openings in a convex protrusion with opaque lateral surfaces. *Id.* at 27:13-41, Fig. 7B. Although Figure 7B only depicts two emitters, the specification describes sensor 101 including an emitter 104, which "can include one or more sources of optical radiation, such as LEDs " Id. at 12:5-9. In one embodiment, "the emitter 104 can emit optical radiation at three (3) or more wavelengths " Id. at 12:35-44. Moreover, the specification discloses that the number of emitters can match the number of detectors in the context of Figure 13, which is described as "an example multi-stream operation of the system of FIG. 1." Id. at 6:45-47, 33:37-39, Fig. 1, Fig. 13. In view of these disclosures, the evidence fails to clearly and convincingly show that the inventors lacked possession of a device with three or more LEDs, three or more photodiodes, and a protrusion with a plurality of openings over the photodiodes with opaque lateral surfaces. Cf. Invidior Inc. v. Dr. Reddy's Labs., S.A., 930 F.3d 1325, 1349 (Fed. Cir. 2019) (finding disclosure "reasonably conveyed to a skilled artisan" the claimed films, and noting that "[t]he specification need not recite the claimed invention in haec verba").

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Accordingly, the undersigned finds that Apple has not shown by clear and convincing evidence that the asserted claims of the Poeze patents are invalid for lack of written description with respect to the limitations requiring three or more LEDs, three or more photodiodes, and a protrusion with a plurality of openings over the photodiodes with opaque lateral surfaces.

2. Four Sets of at Least Three LEDs ('502 patent claim 22)

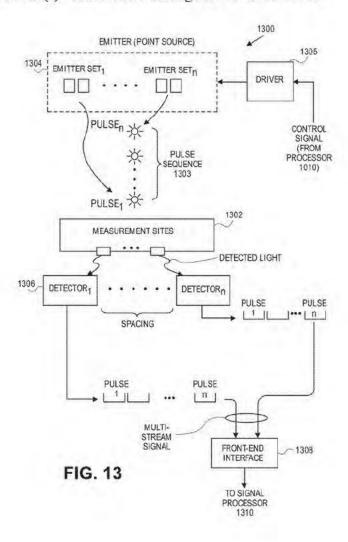
Apple contends that '502 patent claim 22 is invalid for lack of written description, because the specification fails to disclose four sets of at least three LEDs. RIB at 151; RRB at 75. Dr. Warren testified that he found no such disclosure in the specification of the Poeze patents. Tr. (Warren) at 1247:8-12. Apple argues that Figure 7B only depicts two emitters and the specification's reference to "sets of optical sources" is insufficient to disclose the claimed "at least four emitters . . . wherein each of the plurality of emitters comprises a respective set of at least three LEDs." JX-002 at claim 22.

Complainants argue that Dr. Warren's conclusory testimony is insufficient to show lack of written description. CIB at 180. Dr. Madisetti identified disclosures in the specification where multiple emitters are disclosed and the emitters are described as sets of optical sources.

Tr. (Madisetti) at 1349:7-1350:3. In particular, the specification provides that "the emitter 104 can include one or more sources of optical radiation, such as LEDs" JX-001 at 12:5-8. And "[i]n an embodiment, the emitter 104 includes sets of optical sources that are capable of emitting visible and near-infrared optical radiation." *Id.* at 12:9-12. The specification incorporates by reference a patent application, U.S. Application No. 2006/0211924, which describes an array of emitters. *Id.* at 12:16-20. Figure 13 describes sets of emitters that are numbered to match the number of detectors. *Id.* at 33:37-39, Fig. 13.

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Here, the evidence of record fails to show, clearly and convincingly, that four sets of at least three LEDs claimed in '502 patent claim 22 lack written description in the specification of the Poeze patents. Although there is no explicit disclosure of the claimed four sets of at least three LEDs, the specification provides that "the emitter 104 can include one or more sources of optical radiation, such as LEDs" JX-001 at 12:6-9. The specification also provides that the "emitter 104 can include sets of light-emitting diodes (LEDs) as its optical source." JX-001 at 13:16-17; see also id. at 12:9-12 ("In an embodiment, the emitter 104 includes sets of optical sources that are capable of emitting visible and near-infrared optical radiation."). Figure 13 depicts multiple "emitter set(s)" numbered 1 through n. Id. at 33:18-51.



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Id. at Fig. 13. As discussed above, Figure 13 provides written description support for at least four sets of emitters, because the number of emitters matches the number of detectors, and the specification discloses at least four detectors. See id. at 33:37-39, Fig. 13. The specification further provides written description support for three LEDs in each set by referring to "sets of light-emitting diodes (LEDs)" with both "sets" and "LEDs" plural. See id. at 13:16-17; see also id. at 12:9-12 ("sets of optical sources"). Apple has not identified any reason that one of ordinary skill would read the plural "LEDs" as being limited to sets of two, and sets of three or more would be consistent with the disclosure that the emitters can be arranged in an array. See id. at 12:17-25. In view of these disclosures, the evidence fails to clearly and convincingly show that the inventors lacked possession of a device with four sets of at least three LEDs. Cf. Invidior v. Dr. Reddy's Labs., 930 F.3d at 1349.

Accordingly, Apple has not shown by clear and convincing evidence that '502 patent claim 22 is invalid for lack of written description with respect to the claimed four sets of three LEDs.

3. Separate Sets of LEDs Emitting at a First Wavelength and a Second Wavelength ('502 patent claim 28; '648 patent claim 12)

Apple contends that '502 patent claim 28 and '648 patent claim 12 are invalid for lack of written description, because the specification fails to disclose separate sets of LEDs emitting at the same "first wavelength" and "second wavelength." RIB at 151-52; RRB at 75. Dr. Warren testified that he found no disclosure for this limitation in the specification of the Poeze patents.

Tr. (Warren) at 1247:13-17. Apple argues that the specification's reference to "sets of optical"

⁵⁸ U.S. Patent Application Publication No. 2006/0211924 is incorporated by reference as an example of emitters arranged in an array.

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sources" is insufficient to disclose the claimed two sets of LEDs each with "an LED configured to emit light at a first wavelength and an LED configured to emit light at a second wavelength."

JX-002 at claim 28; JX-003 at claim 12.

Complainants argue that Dr. Warren's testimony is conclusory and insufficient to show lack of written description. CIB at 179. Dr. Madisetti identified disclosures in the specification of the Poeze patents "including sets of LEDs with different wavelengths." Tr. (Madisetti) at 1349:7-1350:3. In their briefing, Complainants point to the two emitters depicted in Figures 7A and 7B and the disclosure that "[i]n an embodiment, the emitter 104 includes sets of optical sources that are capable of emitting visible and near-infrared optical radiation." JX-001 at 12:9-12, Fig. 7A, Fig. 7B. Complainants also cite other disclosures describing different arrangements of emitters. See id. at 9:60-63, 12:13-25, 13:16-21, 21:51-54, 33:30-38, 38:8-22.

In consideration of the parties' arguments, the evidence of record shows, clearly and convincingly, that there is insufficient written description support for the limitations in '502 patent claim 28 and '648 patent claim 12 describing two sets of LEDs that each have LEDs emitting light at the same "first wavelength" and the same "second wavelength." This limitation does not merely require that there be two sets of LEDs, each emitting light at two different wavelengths—the claim language requires matching wavelengths in each set of LEDs, and there is no such disclosure in the specification of the Poeze patents. Complainants primarily rely on a disclosure in the specification that "[i]n an embodiment, the emitter 104 includes sets of optical sources that are capable of emitting visible and near-infrared optical radiation." JX-001 at 12:9-12; CIB at 180. Another part of the specification describes an embodiment where "the plurality of sets of optical sources may each comprise at least one top-emitting LED and at least one super luminescent LED." *Id.* at 9:60-62. But while these portions of the specification describe sets of

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LEDs that are capable of emitting at different wavelengths, there is no disclosure of two separate sets of LEDs using the same wavelengths in each set.⁵⁹

The specification repeatedly describes multiple wavelengths of light in sets of LEDs, but there is no disclosure of matching wavelengths between sets of LEDs. When describing emitters that are capable of emitting visible and near-infrared optical radiation, the specification describes two different wavelengths, three different wavelengths, or up to eight different wavelengths. *Id.* at 12:60-13:7. The specification does not describe any two LEDs having the same wavelength, however, instead emphasizing "a variety of wavelengths of visible or near-infrared optical radiation." *Id.* Similarly, when describing emitters using super luminescent LEDs and top emitting LEDs, the specification describes the different capabilities of these LEDs. *See id.* at 13:16-25 (describing "top-emitting LEDs emitting light at about 850 nm to 1350 nm" for optical radiation and "SLEDs or side-emitting LEDs to transmit near infrared optical radiation because these types of sources can transmit at high power or relatively high power.").

Consistent with Dr. Warren's testimony, these disclosures would not convey to persons of ordinary skill in the art that sets of LEDs with matching wavelengths were part of the alleged invention—there is no suggestion that two LEDs emit the same wavelengths or any benefit ascribed to such a pairing. This is similar to the claim limitation that was found invalid for lack of written description in *Purdue Pharma L.P. v. Faulding Inc.*, where the Federal Circuit found "nothing in the written description . . . that would suggest to one skilled in the art that the [claimed] ratio is an important defining quality of the formulation, nor does the disclosure even

As discussed above in the context of obviousness, LEDs meeting this limitation are explicitly disclosed in the prior art in Lumidigm. *See* RX-0411 at 6:43-48. The Federal Circuit has held, however, that "it is

the specification itself that must demonstrate possession," and "a description that merely renders the invention obvious does not satisfy the requirement." *Ariad Pharms.*, *Inc.* v. *Eli Lilly & Co.*, 598 F.3d

1336, 1352 (Fed. Cir. 2010).

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motivate one to calculate the ratio." 230 F.3d 1320, 1327 (Fed. Cir. 2000); see also Ariad, 598 F.3d at 1352 (noting that a description that "merely renders the invention obvious does not satisfy the requirement").60

Accordingly, the evidence shows, clearly and convincingly, that '502 patent claim 28 and '648 patent claim 12 are invalid for lack of written description.

4. Touch-Screen Display ('502 patent claim 28)

Apple contends that '502 patent claim 28 is invalid for lack of enablement, because the specification fails to enable a "touch-screen display" that "displays indicia responsive" to any "measurement." RIB at 152; RRB at 75-76. Dr. Warren testified that he only found two brief references to touch-screens in the patent specification. Tr. (Warren) at 1247:18-23. Apple argues that these disclosures are insufficient to enable a person of ordinary skill in the art to use a touch-screen on a user-worn device to display an oxygen saturation measurement. RIB at 152. Complainants argue that the specification discloses a touch-screen as one example of a user interface and further provides that physiological measurements can be shown on a display. CIB at 181-82; CRB at 104; see Tr. (Madisetti) at 1352:5-24, 1381:7-1382:8.

⁶⁰ Complainants argue that Dr. Warren's testimony at hearing was conclusory, but the specification clearly supports Dr. Warren's testimony that there is no disclosure in the specification of two sets of LEDs with matching wavelengths. See Tr. (Warren) at 1247:13-17. And Dr. Madisetti did not address this limitation in his rebuttal testimony, only identifying disclosures in the specification describing "sets of LEDs with different wavelengths" but failing to offer any opinion as to whether these disclosures support the claimed two sets of LEDs using the same two wavelengths. See Tr. (Madisetti) at 1349:7-1350:3, 1350:22-1352:4. Moreover, the written description analysis is not limited to expert testimony. See, e.g., University of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916, 927 (Fed. Cir. 2004) ("[A] patent can be held invalid for failure to meet the written description requirement, based solely on the language of the patent specification. After all, it is in the patent specification where the written description requirement must be met.").

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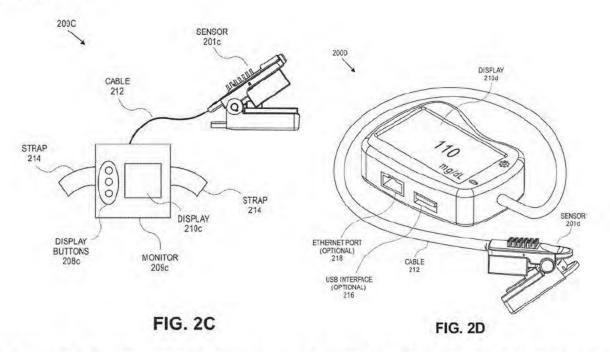
In consideration of the parties' arguments, the undersigned finds that the evidence fails to show, clearly and convincingly, the lack of an enabling disclosure for the claimed "touch-screen display" in the specification of the Poeze patents.

To prove a claim is invalid for lack of enablement, "a challenger must show by clear and convincing evidence that a person of ordinary skill in the art would not be able to practice the claimed invention without 'undue experimentation." Amgen Inc. v. Sanofi, Aventisub LLC, 987 F.3d 1080, 1084 (Fed. Cir. 2021) (internal quotations omitted). Whether undue experimentation is needed is "not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." Id. (quoting In re Wands, 858 F.2d 731, 736-37 (Fed. Cir. 1988)). The "Wands" factors are: "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." Id. at 1084. The Federal Circuit has stated that "after the challenger has put forward evidence that some experimentation is needed to practice the patented claim, the factors set forth in Wands then provide the factual considerations that a court may consider when determining whether the amount of that experimentation is either 'undue' or sufficiently routine such that an ordinarily skilled artisan would reasonably be expected to carry it out." Amgen, 987 F.3d at 1084-85.

Here, Apple has not presented any argument regarding the majority of the *Wands* factors, instead citing to a single sentence of expert testimony regarding the lack of explicit guidance in the specification. Apple does not provide, for example, any supporting evidence regarding the state of the prior art with respect to touchscreens and their use, or the quantity of experimentation

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necessary. Further, the specification discloses a monitoring device 200a that includes a display 210a and "can employ any of a variety of user interface designs, such as frames, menus, touch-screens, and any type of button." JX-001 at 17:20-26. The specification also discloses a monitor 209b, which "can include display 210b that can indicate a measurement for glucose," and "[o]ther analytes and forms of display can also appear on the monitor 209b." *Id.* at 17:67-18:3. This monitor is part of the claimed user-worn device, as "the monitor 209b can include a belt clip or straps (see, e.g., FIG. 2C) that facilitate attachment to a patient's belt, arm, leg, or the like." *Id.* at 17:56-59.



Id. at Fig. 2C, Fig. 2D. Although these features are described in the context of different figures, the specification provides that "certain of the features of the monitoring devices 200 shown in FIGS. 2A through 2D can be combined with features of the other monitoring devices shown."

Id. at 16:39-42. Dr. Madisetti reviewed the disclosures of the patent and testified that "the

⁶¹ To the contrary, Dr. Warren elsewhere testified that a touchscreen "could be incorporated in any visual depiction for a portable device." Tr. (Warren) at 1226:25-1227:7.

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touchscreen display and indicia of measurement are fully enabled in the asserted claims." Tr. (Madisetti) at 1381:7-1382:8.

In view of the above, Apple has not shown, clearly and convincingly, that '502 patent claim 28 is invalid for lack of enablement with respect to the claimed "touch-screen display."

5. Light Piping ('501 patent claim 12, '502 patent claim 28, '648 patent claim 24)

Apple contends that '501 patent claim 12, '502 patent claim 28, and '648 patent claim 24 are invalid for lack of enablement with respect to limitations describing opaque surfaces that "avoid" or "reduce" "light piping." RIB at 152-53; RRB at 76. Apple further contends that '648 patent claim 24 is invalid for lack of written description with respect to being "configured to substantially prevent light piping." *Id.* Dr. Warren testified that the specification only provides "a vague correlation" between the use of opaque materials and the reduction of light piping. Tr. (Warren) at 1247:24-1248:4.

Complainants argue that Dr. Warren's conclusory testimony is insufficient to meet Apple's clear and convincing burden. CIB at 182. Complainants submit that the specification explicitly teaches the use of a hard opaque plastic to reduce light piping. *Id.* at 183 (citing JX-0001 at 7:65-8:7, 43:32-36). Complainants further cite an embodiment described in the specification wherein adding height "assists in deflecting light piping through the sensor." JX-0001 at 25:47-62. Dr. Madisetti reviewed these disclosures and offered his opinion that the written description and enablement requirements have been met for each of the "light piping" limitations. Tr. (Madisetti) at 1350:4-21, 1352:25-1353:11.

In consideration of the parties' arguments, the evidence of record fails to show, clearly and convincingly, that the specification of the Poeze patents fails to enable the "light piping" limitations of the asserted claims or lacks adequate written description with respect to '648

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patent claim 24. As with the "touchscreen" arguments, Apple has not presented any argument regarding the majority of the *Wands* factors, instead citing to a single sentence of expert testimony regarding the lack of explicit guidance in the specification. *See* RIB at 152-53; CRB at 104-105. Moreover, the specification explicitly teaches that "[t]he protrusion can advantageously include plastic, including a hard opaque plastic, such as a black or other colored plastic, helpful in reducing light noise," and "[s]uch light noise includes light piping." JX-0001 at 7:65-8:7. In reference to the Figure 3 embodiments, a "noise shield" is disclosed that "may be configured to reduce noise, such as from ambient light and electromagnetic noise." *Id.* at 43:30-33. The specification provides that the noise shield "may be constructed from materials having an opaque color, such as black or a dark blue, to prevent light piping." *Id.* at 43:33-36. This teaching is also referenced in the context of Figures 7A and 7B, where the specification describes a "shielding enclosure" that "can include an opaque material to not only reduce electrical noise, but also ambient optical noise." *Id.* at 27:1-3.62 *See generally* CIB at 182-183.

In view of the above, Apple has failed to show by clear and convincing evidence that any asserted claims are invalid for lack of enablement with respect to the "light piping" limitations.

Further, the undersigned finds that Apple has not shown by clear and convincing evidence that '648 patent claim 24 is invalid for lack of written description with respect to being "configured to substantially prevent light piping." Apple's written description argument is unclear and appears to be based on the same issues discussed with regard to enablement. *See* RIB at 152-53. For the reasons discussed *supra*, including the specification's descriptions

⁶² In another embodiment where "an extension" is used "to increase the height of [a] partially cylindrical protrusion," "the added height assists in deflecting light piped through the sensor." JX-001 at 25:43-62.

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regarding light piping and the lack of sufficient expert testimony or other record evidence, Apple has not met its burden.

I. Prosecution Laches and Unclean Hands

Apple argues that the Poeze patents are unenforceable due to prosecution laches and the doctrine of unclean hands because of Complainants' delays in patent prosecution. RIB at 153-59; RRB at 77-79.

Apple submits that the provisional applications that led to the Poeze patents were filed in July and August 2008, and Masimo continued to file related continuations and continuations-in-part through July 2010. *See* JX-001; JX-002; JX-003. After a five-year gap (and after the first Apple Watch was released), Masimo filed a new continuation application in December 2015. *See* U.S. Patent App. No. 14/981,290 (cited in JX-001; JX-002; JX-003). Masimo then filed several additional continuation applications between December 2018 and March 2020,⁶³ and then filed the applications leading to the three asserted Poeze patents on September 24, 2020, within days of the release of the Apple Watch Series 6. *See* JX-001; JX-002; JX-003; RX-0333 (9/15/20 press release announcing Apple Watch Series 6).

Apple argues that the twelve-year delay between the 2008 filings of the original provisional applications and the 2020 filings of the continuation applications for the Poeze patents warrants a determination that the patents are unenforceable due to prosecution laches.

RIB at 153-59. Apple submits that Masimo has provided no credible explanation for the long delay in filing the continuation applications and that the totality of the circumstances shows that Masimo lacked diligence in prosecuting the Poeze patents. *Id.* at 155-57. Apple argues that the

⁶³ Apple argues that these continuation applications were filed after the release of version of the Apple Watch in 2018 and 2019. *See RDX-1.16*.

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timing of Masimo's patent application filings shows that the delays in prosecution were intentional—taking advantage of the growth in the market for wearable technology and allowing Masimo to draft claims targeting Apple Watch products after their release. *Id.* at 156-57.

Apple submits that it has suffered prejudice due to Masimo's patent prosecution delays, because Apple invested heavily in the development of the Apple Watch products, including the blood oxygen feature. RIB at 157-58; RRB at 78. Apple argues that Masimo gained an improper litigation advantage by waiting to draft its patent claims until after the release of the Apple Watch Series 6, noting that the prosecuting attorney for the Poeze patents admitted that he had of the Apple Watch Series 6 during prosecution. See Tr. (Cromar) at 1031:13-22. Apple argues that the prosecution of other patents in the family of the Poeze patents is irrelevant to the inquiry into whether Masimo was diligent with respect to the prosecution of the asserted Poeze patents. RRB at 77-78.

Apple argues that Masimo's conduct with respect to the prosecution of the Poeze patents meets the legal requirements for unenforceability due to prosecution laches and also that this conduct should bar Complainants' claims for relief in this investigation under the doctrine of unclean hands. RIB at 158-59; RRB at 77-79.

Complainants argue that Apple has failed to meet its burden with respect to prosecution laches or unclean hands. CIB at 183-85; CRB at 105-108. Complainants submit that the prosecution of applications in the family of the Poeze patents was continuous throughout the alleged 12-year period identified by Apple. CIB at 183-84. Mr. Cromar testified that there were "a dozen applications being actively prosecuted" during the alleged five-year "gap" between 2010 and 2015. Tr. (Cromar) at 1039:7-12. Complainants' expert on PTO practice and procedure, Robert Stoll, testified that there was a "continuous unbroken chain of patent

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prosecution" in the family of the Poeze patents. Tr. (Stoll) at 1415:2-10. Complainants argue that the legal precedent requires considering diligence with respect to all of these related patent applications. CRB at 106. Complainants dispute Apple's timeline tying patent application filings to versions of the Apple Watch, which were released every year from 2015 to 2020. *Id.* at 106-107. Complainants argue that there is nothing improper about drafting claims to cover competitors' products. *Id.* at 107-108. Complainants further argue that there can be no prejudice to Apple because the specification of the Poeze patents was published in February 2010. *See* CX-0137 (U.S. Patent Pub. No. 2010/0030040).

In consideration of the parties' arguments, the undersigned finds that Apple has not carried its burden to show that the Poeze patents should be found unenforceable due to prosecution laches or unclean hands. To establish a defense of prosecution laches, an accused infringer must show: (1) that the patentee's delay in prosecution was unreasonable and inexcusable under the totality of circumstances, and (2) that the accused infringer suffered prejudice attributable to the delay. *Cancer Rsch. Tech. Ltd. v. Barr Labs., Inc.*, 625 F.3d 724, 728-29 (Fed. Cir. 2010). The Federal Circuit has held that "an examination of the totality of the circumstances[] include[s] the prosecution history of all of a series of related patents." *Symbol Techs., Inc. v. Lemelson Med., Educ. & Rsch. Found.*, 422 F.3d 1378, 1386 (Fed. Cir. 2005) ("Symbol Techs.").

Here, the record evidence is insufficient to support a finding of unreasonable or inexcusable delay with respect to the prosecution of the Poeze patents. Apple cites a five-year delay in the filing of continuation applications between 2010 and 2015, but there was continuous prosecution activity in the family of the Poeze patents during this time. *See* Tr. (Cromar) at

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1038:7-19.64 The fact that the 2015 continuation application could have been filed earlier is not a sufficient basis for finding of prosecution laches, as the Federal Circuit has recognized that "[t]here are legitimate grounds for refiling a patent application which should not normally be grounds for a holding of laches, and ... [t]he doctrine should be applied only in egregious cases of misuse of the statutory patent system. Symbol Techs., 422 F.3d at 1385. The next application in the Poeze patent family was a divisional application (U.S. Patent Application No. 16/212,537) filed in December 2018, and the Federal Circuit has held that "[f]iling a divisional application in response to a requirement for restriction" is a "legitimate reason for refiling a patent application. . . even when one defers the filing of a divisional application until just before the issuance of the parent application." Id. In the context of this continuous prosecution activity in the family of the Poeze patents, Apple's arguments tying certain patent application filings to release dates for the Apple Watch is unpersuasive. See RDX-1C.16. Apple has failed to identify actions by Masimo that resemble the type of conduct recognized by the Federal Circuit as unjustifiable prosecution delay, such as refiling applications containing previously-allowed claims, repetitive filing of applications that were merely placeholders, or a "consistent pattern of receiving a rejection on an application, filing a continuation application without any amendments, and abandoning the original application." See Hyatt v. Hirshfeld, 998 F.3d 1347, 1361-62, 1366-69 (Fed. Cir.

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⁶⁴ U.S. Patent Application No. 12/497,523, filed on July 2, 2009, issued as U.S. Patent No. 8,347,825 on May 7, 2013; U.S. Patent Application No. 12/497/528, filed on July 2, 2009, issued as U.S. Patent No. 8,577,431 on November 5, 2013; and U.S. Patent Application No. 12/829,352, filed on July 1, 2010, issued as U.S. Patent No. 9,277,880 on March 8, 2016. *See* JX-0001 (identifying continuation applications); JX-004 at 418-26 (information disclosure statement identifying Masimo's pending patent applications and issued patents).

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2021).⁶⁵ The record evidence in this investigation is insufficient to support a finding of prosecution laches.

Moreover, because the undersigned does not find evidence of bad faith conduct by

Masimo during the prosecution of the Poeze patents, there is no basis for any finding of unclean
hands. Apple's unclean hands defense is based solely on Masimo's alleged misconduct during
the prosecution of the Poeze patents, RIB at 158-59, and Apple does not argue that any particular
conduct would be the basis for a finding of unclean hands without a finding of inequitable
conduct.

V. U.S. PATENT NO. 10,687,745

The '745 patent is entitled "Physiological Monitoring Devices, Systems, and Methods," naming inventor Ammar Al-Ali and issuing from an application filed on March 31, 2020, claiming priority to a provisional application filed on July 2, 2015, and a non-provisional application filed on June 28, 2016. JX-009.

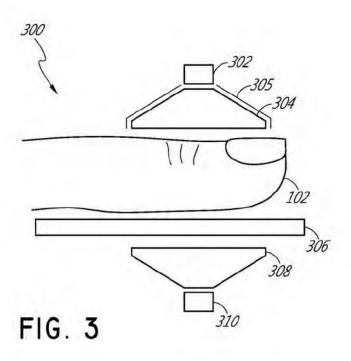
A. Specification

The specification of the '745 patent describes a method for pulse oximetry wherein an emitter irradiates a surface area on the skin. *See* JX-009 at 6:21-54, Fig. 2. The patent refers to this method as "three-dimensional (3D) pulse oximetry in which the emitted light irradiates a larger volume of tissue . . . as compared to the 2D point optical source approach." *Id.* at 6:21-26.

during prosecution, Tr. (Cromar) at 1031:13-22, but the Federal Circuit has held that "there is nothing improper, illegal or inequitable in filing a patent application for the purpose of obtaining a right to exclude a known competitor's product from the market; nor is it in any manner improper to amend or insert claims intended to cover a competitor's product the applicant's attorney has learned about during the prosecution of a patent application." *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 874 (Fed. Cir. 1988). Moreover, Apple has not provided evidence showing that newly asserted claim limitations were specifically drawn to the Accused Products.

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In one embodiment, a "light diffuser 304 receives the optical radiation emitted from the emitter 302 and spreads the optical radiation over an area." *Id.* at 7:42-44.

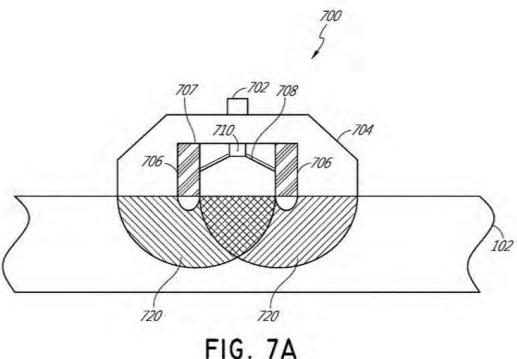


Id. at Fig. 3. The specification provides examples of the diffuser distributing light "in a predefined geometry (e.g., a rectangle, square, or circle)." Id. at 8:9-12. The specification further describes a "light concentrator 308," which "is a structure to receive the emitted optical radiation, after attenuation by the tissue measurement site 102." Id. at 9:11-18.

In a separate embodiment, a "3D sensor 700 can be placed on a portion of the patient's body that has relatively flat surface, such as, for example a wrist, because emitter 702 and detector 710 are located on the same side of the tissue measurement site 102." *Id.* at 10:40-51.

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Id. at Fig. 7A. This embodiment includes a "light diffuser 704" that "receives the optical radiation emitted from the emitter 702 and homogenously spreads the optical radiation over a wide, donut-shaped area." Id. at 10:65-11:9, Fig. 7B. This embodiment further comprises a "light blocker 706" that "includes an annular ring having a cover portion 707 sized and shaped to form a light isolation chamber for the light concentrator 708 and the detector 710." Id. at 11:11-13.

Claims B.

Complainants assert infringement of claims 9 and 27, and they rely on claim 18 for domestic industry. Claim 9 depends from claim 1, recited below:

- 1. A physiological monitoring device comprising:
- a plurality of light-emitting diodes configured to emit light in a first shape;
- a material configured to be positioned between the plurality of light-emitting diodes and tissue on a wrist of a user when the physiological monitoring device is in use, the material configured to change the first shape into a second shape

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by which the light emitted from one or more of the plurality of light-emitting diodes is projected towards the tissue;

- a plurality of photodiodes configured to detect at least a portion of the light after the at least the portion of the light passes through the tissue, the plurality of photodiodes further configured to output at least one signal responsive to the detected light;
- a surface comprising a dark-colored coating, the surface configured to be positioned between the plurality of photodiodes and the tissue when the physiological monitoring device is in use, wherein an opening defined in the dark-colored coating is configured to allow at least a portion of light reflected from the tissue to pass through the surface;
- a light block configured to prevent at least a portion of the light emitted from the plurality of light-emitting diodes from reaching the plurality of photodiodes without first reaching the tissue; and
- a processor configured to receive and process the outputted at least one signal and determine a physiological parameter of the user responsive to the outputted at least one signal.

JX-009 at 15:31-61.

9. The physiological monitoring device of claim 1, wherein the physiological parameter comprises oxygen saturation.

Id. at 16:21-23. Claim 18 depends from claim 15, recited below:

- 15. A physiological monitoring device comprising:
- a plurality of light-emitting diodes configured to emit light proximate a wrist of a user:
- a light diffusing material configured to be positioned between the plurality of light-emitting diodes and a tissue measurement site on the wrist of the user when the physiological monitoring device is in use;
- a light block having a circular shape;
- a plurality of photodiodes configured to detect at least a portion of the light emitted from the plurality of light-emitting diodes after the light passes through the light diffusing material and a portion of the tissue measurement site encircled by the light block, wherein the plurality of photodiodes are arranged in an array having a spatial configuration corresponding to a shape of the portion of the tissue measurement site encircled by the light block, wherein the plurality of photodiodes are further configured to output at least one signal

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responsive to the detected light, and wherein the plurality of light-emitting diodes and the plurality of photodiodes are arranged in a reflectance measurement configuration;

- wherein the light block is configured to optically isolate the plurality of lightemitting diodes from the plurality of photodiodes by preventing at least a portion of light emitted from the plurality of light-emitting diodes from reaching the plurality of photodiodes without first reaching the portion of the tissue measurement site:
- a processor configured to receive and process the outputted at least one signal and determine a physiological parameter of the user responsive to the outputted at least one signal; and
- wherein the physiological monitoring device is configured to transmit physiological parameter data to a separate processor.

Id. at 16:36-17:3.

- 18. The physiological monitoring device of claim 15, wherein the physiological parameter comprises oxygen saturation.
- Id. at 17:10-12. Claim 27 depends from claim 20, recited below:
 - 20. A system configured to measure one or more physiological parameters of a user, the system comprising:
 - a physiological monitoring device comprising:
 - a plurality of light-emitting diodes configured to emit light in a first shape;
 - a material configured to be positioned between the plurality of light-emitting diodes and tissue of the user when the physiological monitoring device is in use, the material configured to change the first shape into a second shape by which the light emitted from one or more of the plurality of light-emitting diodes is projected towards the tissue;
 - a plurality of photodiodes configured to detect at least a portion of the light after the at least the portion of the light passes through the tissue, the plurality of photodiodes further configured to output at least one signal responsive to the detected light;
 - a surface comprising a dark-colored coating, the surface configured to be positioned between the plurality of photodiodes and the tissue when the physiological monitoring device is in use, wherein an opening defined in the dark-colored coating is configured to allow at least a portion of light reflected from the tissue to pass through the surface;

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- a light block configured to prevent at least a portion of light from the plurality of light-emitting diodes from reaching the plurality of photodiodes without first reaching the tissue; and
- a processor configured to receive and process the outputted at least one signal and determine a physiological parameter of the user responsive to the outputted at least one signal; and
- a processing device configured to wirelessly receive physiological parameter data from the physiological monitoring device, wherein the processing device comprises a user interface, a storage device, and a network interface configured to wirelessly communicate with the physiological monitoring device, and wherein the user interface includes a touch-screen display configured to present visual feedback responsive to the physiological parameter data.

Id. at 17:20-18:18.

27. The system of claim 20, wherein at least one of the plurality of light-emitting diodes is configured to emit light of a first wavelength and at least one of the plurality of light-emitting diodes is configured to emit light of a second wavelength, the second wavelength being different than the first wavelength.

Id. at 16:21-23.

C. Level of Ordinary Skill in the Art

The parties have stipulated to the same level of ordinary skill in the art for the '745 patent as the Poeze patents:

[A] person with a working knowledge of physiological monitoring technologies. The person would have had a Bachelor of Science degree in an academic discipline emphasizing the design of electrical, computer, or software technologies, in combination with training or at least one to two years of related work experience with capture and processing of data or information, including but not limited to physiological monitoring technologies. Alternatively, the person could have also had a Master of Science degree in a relevant academic discipline with less than a year of related work experience in the same discipline.

Joint Stipulation of Facts ¶ 10, EDIS Doc. ID 770692 (May 13, 2022).

D. Claim Construction

The parties dispute the construction of the term "second shape" in claims 1 and 20, but they agree that the differences between their proposed constructions do not affect any disputed

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issue. See CIB at 185-86; RIB at 163-64. Accordingly, this term shall be construed to have its plain and ordinary meaning, which the parties agree is "a shape different from the first shape." See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc., 200 F.3d 795, 803 (Fed. Cir. 1999) (Claims must be construed "only to the extent necessary to resolve the controversy.").

E. Infringement

Complainants allege that the Accused Products infringe claims 9 and 27 of the '745 patent, relying on a theory of induced infringement with respect to claim 27. CIB at 188-202. Apple only disputes infringement with respect to the "first shape" and "second shape" limitations. RIB at 164-73; RRB at 81-88. For the reasons discussed below, the undersigned finds that Complainants have not shown, by a preponderance of the evidence, that the Accused Products infringe claims 9 or 27 of the '745 patent.

1. '745 Patent Claim 9

a. Element [1 preamble]: "A physiological monitoring device comprising"

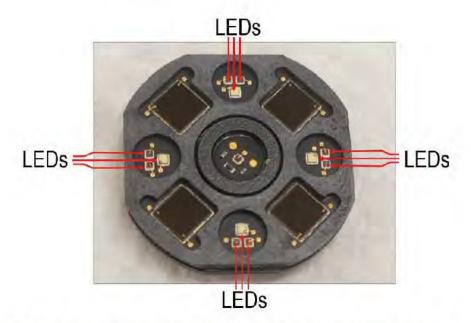
There is no dispute that each of the Accused Products is a "physiological monitoring device" as required by the preamble of claim 1. *See* CIB at 188.⁶⁶ Dr. Madisetti identified evidence that the Accused Products are devices that can measure blood oxygen. Tr. (Madisetti) at 729:24-730:6; CDX-0011C.073; CX-0241C (Apple Watch Series First Look); CX-1532 at 4-5 (Apple Watch Series 6 Press Release); CX-1447 at 7 (Apple Watch Series 7 website); CX-1449 at 2 (Apple Watch Series 7 website). Accordingly, the evidence of record shows that the preamble limitations are met by the Accused Products.

⁶⁶ The parties have stipulated that the preambles of the asserted patent claims are limiting. *See* Joint Stipulation of Facts ¶ 9, EDIS Doc. ID 770692 (May 13, 2022).

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b. Element [1A] "a plurality of light-emitting diodes configured to emit light in a first shape"

There is no dispute that each of the Accused Products has a plurality of light-emitting diodes emitting light in a shape. *See* CIB at 188-90. Dr. Madisetti identified four sets of red, infrared, and green LEDs on the sensor board of the Accused Products. Tr. (Madisetti) at 730:7-731:1.

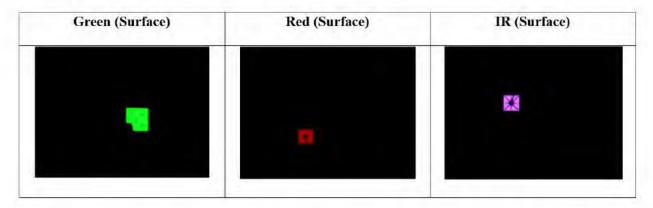


CDX-0011C.074 (labeling LEDs on CX-1548C at 37); see also CX-0281C (Block Dep. Tr.) at 83:11-85:16 (identifying LEDs in the Accused Products); Tr. (Mehra) at 855:4-856:14 (describing LEDs in the Accused Products); CX-0057C at 2 (Series 6 schematic); CX-0059C at 2 (Series 7 schematic).

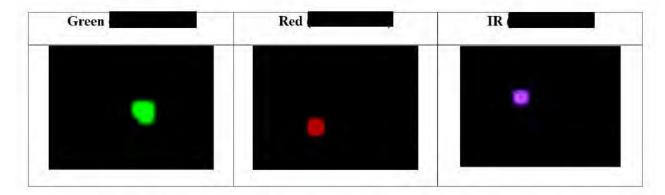
Dr. Madisetti also used a camera to capture images of the light emitted by the LEDs in the Accused Products. Tr. (Madisetti) at 724:14-729:23, 730:7-731:1.

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CDX-0011C.074 (citing CX-1546C at 5, 15, 1); CIB at 189-90. Dr. Madisetti also captured images of the light 2mm from the LEDs—before passing through a Tr. (Madisetti) at 745:5-25.



CX-1546C at 5, 15, 1; see CDX-0011C.091; CIB at 189-90.⁶⁷ There is no dispute that this light is emitted in a shape, and accordingly, the evidence of record shows that this limitation is met.

⁶⁷ As discussed *infra* in the context of the "material" limitation, the relevant "first shape" is the shape of the light before passing through the lens.

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c. Element [1B]: "a material configured to be positioned between the plurality of light-emitting diodes and tissue on a wrist of a user when the physiological monitoring device is in use, the material configured to change the first shape into a second shape by which the light emitted from one or more of the plurality of light-emitting diodes is projected towards the tissue"

With respect to the "material configured to be positioned between the plurality of lightemitting diodes and tissue on a wrist of a user," Dr. Madisetti identified a

that is positioned between the LEDs and the wrist of the user. Tr. (Madisetti) at
731:25-732:24; CDX-0011C.076. Dr. Madisetti used a camera to capture images of the light
2mm from the LEDs—before passing through

Tr. (Madisetti) at 745:5-25;
CDX-0011C.091 (citing CX-1546C at 5, 15, 1). He also captured images of the light after
passing through

and compared the shape of the light at three locations—at the LEDs,
before

and after

Tr. (Madisetti) at 732:25-733:18, 747:3-12.

	Surface	Before	After
Red	n		
Green	•		
IR	o		39

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CDX-0011C.091 (citing CX-154C at 1, 5, 15). He offered his opinion that the "first shape" at the surface of the LEDs and before is different from the "second shape" after Tr. (Madisetti) at 732:25-733:18, 747:3-12. He testified at the hearing: "So you can see clearly with our naked eye that the shapes before , which is the first shape, and the second shape, which is after , are different." *Id.* at 733:15-17.

Apple argues that this limitation is not infringed for two reasons: (1) the "first shape" emitted by the LEDs is not the same "first shape" entering and (2) is not configured to change the "first shape" into a "second shape." RIB at 164-73; RRB at 81-88. These two issues are addressed separately below:

(i) "first shape"

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polygon." *Id.* at 1115:25-1116:11. He described the shape of the light received by "more of a closer to a circle shape" and a "convex polygon." *Id.* Relying on "fundamentals of geometry," he testified that "concave polygons are fundamentally different from convex polygons." *Id.* He offered his opinion that "the shape that is emitted at the surface of LED is fundamentally different from the shape that is received by as we saw in the three examples, and we know that because of physics." *Id.* at 1116:23-1117:8.

Complainants disagree with Apple's interpretation of this claim language, arguing that the designation of the "first shape" in the claims does not require that the shape be unchanged between the LEDs and ... CIB at 186. Complainants submit that the specification only discusses changes in shape caused by the "beam shaper" that receives light from the LEDs before reaching the user's skin. See JX-009 at 7:42-56. Complainants identify a gap between the light emitter and the beam shaper depicted in Figure 3 of the specification, arguing that Apple's interpretation of the claim language would exclude this embodiment. CIB at 187; see JX-009 at Fig. 3. Dr. Madisetti reviewed the disclosures in the specification and offered his opinion that the claims "do not require the material to receive light in the same shape that was emitted by the LEDs." Tr. (Madisetti) at 746:13-747:2. Complainants argue that the "first shape" is any shape emitted from the LEDs in between the LEDs and the material. See CRB at 110 ("In the claims, the 'first shape' refers to any shape of light emitted by the LEDs before the claimed 'material' changes it into a second shape.").

In consideration of the parties' arguments, the undersigned finds that the language of claim 1 does not require that the emitted light has the same "first shape" at the surface of the LEDs as it has at the surface of the "material configured to change the first shape into a second shape." The first limitation of the claim provides that the LEDs are "configured to emit light in a

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first shape," but the term "emit" is not necessarily limited to the surface of the LEDs. There is light "emitted" from the LEDs described in several other limitations of the claim—light that has been changed into a second shape is described as "light emitted from one or more of the plurality of light-emitting diodes," and certain light that is affected by the light block is also described as "light emitted from the plurality of light-emitting diodes." *See* JX-009 at 15:38-41, 15:54-57. Accordingly, while Apple has offered a plausible interpretation of the claim language to refer to the shape of light at the surface of the LEDs, it is clear from other limitations of the claim that the term "emit" is not limited to this meaning. ⁶⁸

The specification of the '745 patent supports this interpretation of the "first shape" limitation. When describing the Figure 3 embodiment that is shown with a gap between the emitter and the light diffuser, the specification provides that "[t]he light diffuser 304 receives the optical radiation emitted from the emitter 302 and spreads the optical radiation over an area." JX-009 at 7:42-44, Fig. 3. The same language is used in the context of Figure 7A, which does not show a gap between the emitter and the light diffuser: "The light diffuser 704 receives the optical radiation emitted from the emitter 702 and homogenously spreads the optical radiation over a wide, donut-shaped area." *Id.* at 10:65-11:2, Fig. 7A. In both embodiments the light "emitted from" the LEDs is the light received at the light diffuser, which takes this light and spreads it into a wide shape. The spreading and/or shaping of light by the light diffuser is

⁶⁸ Claim 15 also refers to light that has passed through a light diffusing material as "light emitted from one or more of the plurality of light-emitting diodes," and certain light that is affected by the light block is also described as "light emitted from the plurality of light-emitting diodes." *See* JX-009 at 16:44-63.

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emphasized in the specification,⁶⁹ and there is no discussion in the specification of the shape of the light at the surface of the LEDs.

The undersigned thus finds that the reading of the "first shape" limitation that most naturally aligns with the patent's description of the invention is that the light emitted by the LEDs in a "first shape" refers to the shape of the light that is received by the light diffuser, *i.e.* the claimed "material," which is "configured to change the first shape into a second shape." The undersigned thus finds that both Complainants' and Apple's proposed constructions are incorrect. The "first shape" does not refer to "any" shape of the light between the LEDs and the light diffuser, as proposed by Complainants (*see* CRB at 110), and there is no separate requirement that the shape of the light at the surface of the LEDs be the same as the shape of the light that is received by the light diffuser, as proposed by Apple. Accordingly, there is no basis for Apple's non-infringement argument regarding the "first shape."

(ii) "second shape"

With respect to the "second shape," Apple submits that is not configured to change the shape of the light passing through it. RIB at 170-73; RRB at 86-87. Dr. Venugopal testified that "

." Tr. (Venugopal) at 831:4-9. With respect to the shape of the light passing through , he testified that "

." Id. Reviewing Dr. Madisetti's images of the light before and after

⁶⁹ The specification describes "the disclosed systems, devices and methods to implement three-dimensional (3D) pulse oximetry in which the emitted light irradiates a larger volume of tissue at the measurement site 102 as compared to the 2D point optical source approach," which is described as "conventional pulse oximetry." JX-009 at 6:21-25, 5:41-43, Fig. 1, Fig. 2.

⁷⁰ The cases that Apple cites regarding antecedent basis are consistent with this construction, *see* RIB at 164, because the two limitations of the claim refer to the same "first shape."

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Dr. Sarrafzadeh offered his opinion that these were the same shape: "the input to shapes are more or less a circular form, and as they exit they are also more or less a circular form." Tr. (Sarrafzadeh) at 1118:1-11. Dr. Sarrafzadeh acknowledges that there are "dark spots" in the images, but he explains that these are variations in intensity rather than shape. *Id.* at 1119:24-1120:4. Apple further argues that Dr. Madisetti failed to explicitly analyze the difference between the "first shape" before and the "second shape" after RIB at 172-73.

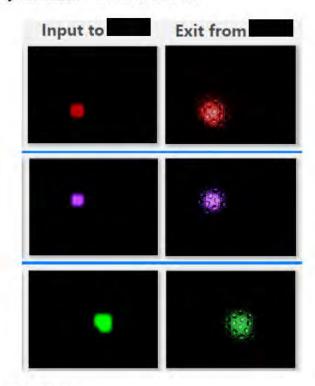
In reply, Complainants cite Dr. Madisetti's testimony that there is a change in shape between the images before and after . See Tr. (Madisetti) at 747:3-12; CDX-0011C.091. Complainants dispute Dr. Sarrafzadeh's analysis of the dark spots in Dr. Madisetti's images and argue that there is no support for his testimony that intensity variations are not a change in shape. CRB at 115. Complainants cite the '745 patent specification's discussion of a circle and donut as distinct shapes, arguing that a shape is not solely defined by its perimeter. JX-009 at 10:65-11:2. Complainants argue that the difference in shape before and after is "self-evident," and "readily apparent." CIB at 194; CRB at 118.

In consideration of the parties' arguments, the undersigned finds that Complainants have failed to carry their burden to prove infringement with respect to the "second shape" limitation. The undersigned agrees with Apple that Dr. Madisetti's analysis with respect to this limitation was unreliable and conclusory. *See* RIB at 160-62. His primary infringement analysis compared the images of the light at the LEDs with images of light after see. , *see* Tr. (Madisetti) at 733:5-18; CDX-0011C.077, but as discussed above, the relevant "first shape" is immediately before that must be configured to change the light from the "first shape" to the "second shape." When Dr. Madisetti compared images of light immediately

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the shape changes." Tr. (Madisetti) at 747:3-12; CDX-0011C.091. Complainants rely on this testimony and argue that the difference between the shapes is "self-evident" or "readily apparent." CIB at 194; CRB at 118. Apple disputes Complainants' contentions, however, and Dr. Sarrafzadeh describes the shapes of the two sets of images as "more or less circular," with shapes that are "relatively the same." *Id.* at 1118:1-24.



RDX-0007.144C (citing CX-0307iC).

The undersigned finds that neither Dr. Madisetti nor Dr. Sarrafzadeh have disclosed a reliable methodology for identifying shapes or determining whether one shape is different from another. Their testimony at hearing comparing the "first shape" images to the "second shape" images was conclusory and unreliable, with Dr. Madisetti failing to even identify the allegedly different shapes that he observed. Indeed, on cross-examination, Dr. Madisetti was presented with several shape outlines and was asked for his opinion on whether the shapes were the same

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or different. Tr. (Madisetti) at 782:6-783:12. Despite Complainants' argument that changes in shape are "self-evident," Dr. Madisetti could not offer an opinion as to whether certain at least somewhat different images represented a change in "shape." *Id.* (stating that he could not say whether RDX-12.3 and RDX-12.5 showed a change in shape); *see also id.* at 1384:23-1385:10 (indicating that images in RDX-12.5 were known to him from his own testing). Dr. Madisetti's inability to compare such shapes underscores the lack of any reliable methodology in his infringement analysis. *See* RIB at 168-69.⁷¹

Moreover, the '745 patent specification describes shapes that are "substantially rectangular, square, circular, oval, or annular, among others." JX-009 at 3:12-14; *see also id.* at 8:9-12 ("a predefined geometry (e.g., a rectangle, square, or circle)"). Another part of the specification describes "a wide, donut-shaped area." *Id.* at 10:65-11:2. The modulate of the light in Accused Products—he only offered conclusory opinions that certain shapes were "different" or observing

The specification indicates that that a diffuser may provide a "defined area shape" only in some embodiments of the invention. See JX-009 at 3:5-14 ("In certain embodiments of the present disclosure, the diffuser comprises glass, ground glass, glass beads, opal glass, or a microlens-based, band-limited, engineered diffuser that can deliver efficient and uniform illumination. In some embodiments, the diffuser is further configured to define a surface area shape by which the emitted spread light is distributed onto a surface of the tissue measurement site. The defined surface area shape can include, by way of non-limiting example, a shape that is substantially rectangular, square, circular, oval, or annular, among others."). This language also indicates that light diffusion, in itself, does not necessarily provide changes in "shape." This is reflected in claim 15 of the '745 patent, which is asserted for domestic industry (as part of dependent claim 18) but not for infringement, requiring a "light diffusing material" without any limitations regarding the shape of the light. Id. at 16:36-17:3.

⁷² All of these references to shapes in the specification refer to the "second shape" after the light diffuser, which is projected on to the skin. There is no discussion of the "first shape" of light before the light diffuser, except in the context of prior art "point optical sources," wherein the measurement site is an "irradiated circular area of the point optical source." JX-009 at 5:54-0, Fig. 1.

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"changes" between images. *See* Tr. (Madisetti) at 733:5-18, 747:3-12.⁷³ The undersigned agrees with Complainants that there are differences in the emitted light before and after , ⁷⁴ but Complainants have failed to present sufficient credible evidence that these differences represent two different "shapes." A preponderance of the evidence does not support a finding that the Accused Products meet this limitation.

In addition, there is no evidence in the record that Apple configured to change the shape of the light. Dr. Venugopal testified that for the Apple Watch Series 6 was designed "

"Tr. (Venugopal) at 826:13-829:14. Apple engineering documents corroborate Dr. Venugopal's testimony—showing that Apple considered

"RX-0895C at 317. Complainants are not required to prove intent with respect to an apparatus claim, but the Apple engineering documents in the record are consistent with Dr. Venugopal's testimony that light passing through

"Tr. (Venugopal) at 831:4-9. It is Complainants' burden to prove that is configured to change the emitted light from a first shape to a second shape, and a preponderance of the evidence does not support a finding that the Accused Products meet this limitation.

⁷³ Although it is not clear that he applied any reliable methodology, Dr. Sarrafzadeh was more willing to describe specific shapes in the images of the Accused Products, such as "a square shape," "square shape-ish," "closer to a circle shape," or "more or less a circular form." Tr. (Sarrafzadeh) at 1115:17-1118:11.

⁷⁴ One visible difference between the images is the pattern of light and dark spots in the "second shape" images. *See* CX-0307iC at 10-21. Dr. Sarrafzadeh stated that the images have "light there, but the cameras don't show them" due to camera "deficiencies." Tr. (Sarrafzadeh) at 1118:4-8, 1119:24-1120:4. Dr. Madisetti's testing shows that there is light in the dark spots when viewed with a lower intensity threshold. CX-0307iC at 11 (images showing no dark spots with "intensity threshold at 0.05"); *see* RRB at 86-87. In any case, it is unclear whether such spots indicate a change in "shape."

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d. Element [1C]: "a plurality of photodiodes configured to detect at least a portion of the light after the at least the portion of the light passes through the tissue, the plurality of photodiodes further configured to output at least one signal responsive to the detected light"

There is no dispute that each of the Accused Products has four photodiodes configured to detect light after it passes through a user's tissue, outputting signals responsive to the detected light. *See* CIB at 196-77; *see* Tr. (Madisetti) at 733:19-734:15; CDX-0011C.078 (citing CX-1548C (Apple Watch Series 7 photograph) at 37; CX-1646C (Apple Watch Series 6 photograph); CX-0059C (Apple Watch Series 7 CAD drawings) at 2; CX-0057C (Apple Watch Series 6 CAD drawings); CX-0281C (Block Dep. Tr.) at 7:21-72:5; CX-0297C (Venugopal Dep. Tr.) at 95:5-96:11; CX-0299C (Waydo Dep. Tr.) at 28:22-29:8). The evidence of record shows that this limitation is met.

e. Element [1D]: "a surface comprising a dark-colored coating, the surface configured to be positioned between the plurality of photodiodes and the tissue when the physiological monitoring device is in use, wherein an opening defined in the dark-colored coating is configured to allow at least a portion of light reflected from the tissue to pass through the surface"

There is no dispute that each of the Accused Products has a surface with a dark-colored coating positioned between the photodiodes and the user's skin, with openings above each photodiode allowing light to pass through. *See* CIB at 197; Tr. (Madisetti) at 734:16-735:18; CDX-0011C.079 (citing CX-0070C (Apple Watch Series 7 Specification) at 5; CX-0068C (Apple Watch Series 6 Specification) at 5; CX-0297C (Venugopal Dep. Tr.) at 188:16-189:1, 192:14-194:15; CX-0291C (Mehra Dep. Tr.) at 105:20-106:14, 111:19-112:8); *see also* Tr. (Block) at 901:13-902:3. The evidence of record shows that this limitation is met.

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f. Element [1E]: "a light block configured to prevent at least a portion of the light emitted from the plurality of light-emitting diodes from reaching the plurality of photodiodes without first reaching the tissue"

There is no dispute that each of the Accused Products has an optical barrier that blocks light from the LEDs from reaching the photodiodes without first reaching the user's tissue. *See* CIB at 198; Tr. (Madisetti) at 735:19-736:19; CDX-0011C.080 (citing CX-0059C (Apple Watch Series 7 CAD drawings) at 1; CX-0057C (Apple Watch Series 6 CAD drawings) at 1; CX-0297C (Venugopal Dep. Tr.) at 92:6-93:3; CX-0281C (Block Dep. Tr.) at 59:5-20, 61:3-6, 81:5-22). The evidence of record shows that this limitation is met.

g. Element [1F]: "a processor configured to receive and process the outputted at least one signal and determine a physiological parameter of the user responsive to the outputted at least one signal"

There is no dispute that each of the Accused Products has a processor that receives and processes signals from the photodiodes and determines an oxygen saturation measurement. *See* CIB at 199; Tr. (Madisetti) at 736:20-737:12; CDX-0011C.081 (citing CX-0013C (ASIC schematic) at 12; CX-0100C (ERS) at 7; CX-0299C (Waydo Dep. Tr. at 38:19-2, 39:2-6, 50:11-14, 68:12-21, 72:10-22, 73:16-19). The evidence of record shows that this limitation is met.

h. Element [9]: "wherein the physiological parameter comprises oxygen saturation"

Claim 9 of the '745 patent depends from claim 1, "wherein the physiological parameter comprises oxygen saturation." There is no dispute that each of the Accused Products measures oxygen saturation. *See* CIB at 199; Tr. (Madisetti) at 737:13-23; CDX-0011C.082 (citing CX-1447 (Apple Watch Series 7 website) at 7; CX-1532 (Apple Watch Series 6 website) at 4). The evidence of record shows that this limitation is met.

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Accordingly, the evidence does not show infringement of claim 9 because Complainants have not proven, by a preponderance, that the Accused Products have a material that is configured to change emitted light from a "first shape" into a "second shape," as required by claim 1.

2. '745 Patent Claim 27

a. Element [20 preamble]: "A system configured to measure one or more physiological parameters of a user, the system comprising: a physiological monitoring device comprising:"

The preamble of claim 20 of the '745 patent requires "[a] system configured to measure one or more physiological parameters of a user," including "a physiological monitoring device." The alleged "system" is an Accused Product in communication with an Apple iPhone. *See* CIB at 199-200. As discussed above in the context of the preamble of '745 patent claim 1, there is no dispute that the Accused Products are devices that can measure blood oxygen. *See* CIB at 201. Moreover, there is no dispute that the Accused Products can be used with an Apple iPhone. *Id*; *see* Tr. (Madisetti) at 738:25-740; CDX-0011C.085 (citing CX-1271 (Apple website) at 1; CX-0010 (Apple website) at 2-3; CX-0299C (Waydo Dep. Tr.) at 74:6-75:17). The evidence of record shows that this limitation is met.

b. Element [20A]: "a plurality of light-emitting diodes configured to emit light in a first shape"

Claim 20 has a "plurality of light-emitting diodes" limitation that is identical to the limitation of claim 1. As discussed above in the context of claim 1, there is no dispute that each of the Accused Products has a plurality of light-emitting diodes emitting light in a shape. See CIB at 201. The evidence of record shows that this limitation is met.

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c. Element [20B]: "a material configured to be positioned between the plurality of light-emitting diodes and tissue of the user when the physiological monitoring device is in use, the material configured to change the first shape into a second shape by which the light emitted from one or more of the plurality of light-emitting diodes is projected towards the tissue"

Claim 20 has a "material configured to change the first shape into a second shape" limitation that is identical to the limitation of claim 1. For the reasons discussed above in the context of claim 1, the undersigned finds that Complainants have not shown that the Accused Products have a material that is configured to change emitted light from a "first shape" into a "second shape."

d. Element [20C]: "a plurality of photodiodes configured to detect at least a portion of the light after the at least the portion of the light passes through the tissue, the plurality of photodiodes further configured to output at least one signal responsive to the detected light"

Claim 20 has a "plurality of photodiodes" limitation that is identical to the limitation of claim 1. As discussed above in the context of claim 1, there is no dispute that each of the Accused Products has four photodiodes configured to detect light after it passes through a user's tissue, outputting signals responsive to the detected light. *See* CIB at 201. The evidence of record shows that this limitation is met.

e. Element [20D]: "a surface comprising a dark-colored coating, the surface configured to be positioned between the plurality of photodiodes and the tissue when the physiological monitoring device is in use, wherein an opening defined in the dark-colored coating is configured to allow at least a portion of light reflected from the tissue to pass through the surface"

Claim 20 has a "surface comprising a dark-colored coating" limitation that is identical to the limitation of claim 1. As discussed above in the context of claim 1, there is no dispute that each of the Accused Products has a surface with a dark-colored coating positioned between the

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photodiodes and the user's skin, with openings above each photodiode allowing light to pass through. *See* CIB at 201. The evidence of record shows that this limitation is met.

f. Element [20E]: "a light block configured to prevent at least a portion of the light emitted from the plurality of light-emitting diodes from reaching the plurality of photodiodes without first reaching the tissue"

Claim 20 has a "light block" limitation that is identical to the limitation of claim 1. As discussed above in the context of claim 1, there is no dispute that each of the Accused Products has an optical barrier that blocks light from the LEDs from reaching the photodiodes without first reaching the user's tissue. *See* CIB at 201. The evidence of record shows that this limitation is met.

g. Element [20F]: "a processor configured to receive and process the outputted at least one signal and determine a physiological parameter of the user responsive to the outputted at least one signal"

Claim 20 has a "processor" limitation that is identical to the limitation of claim 1. As discussed above in the context of claim 1, there is no dispute that each of the Accused Products has a processor that receives and processes signals from the photodiodes and determines an oxygen saturation measurement. *See* CIB at 201. The evidence of record shows that this limitation is met.

h. Element [20G]: "a processing device configured to wirelessly receive physiological parameter data from the physiological monitoring device, wherein the processing device comprises a user interface, a storage device, and a network interface configured to wirelessly communicate with the physiological monitoring device, and wherein the user interface includes a touch-screen display configured to present visual feedback responsive to the physiological parameter data"

There is no dispute that an Apple iPhone is a processing device with a user interface, storage device, and wireless interface that can wirelessly communicate with the Accused

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Products, receive oxygen saturation data and present an oxygen saturation measurement on a touch-screen display. *See* CIB at 201; Tr. (Madisetti) at 740:6-24; CDX-0011C.086 (citing CX-0010C (Apple website) at 5; CX-1492 (Apple website) at 4; CX-0299C (Waydo Dep. Tr.) at 74:11-75:17). The evidence of record shows that this limitation is met.

i. Element [27]: "wherein at least one of the plurality of lightemitting diodes is configured to emit light of a first wavelength and at least one of the plurality of light-emitting diodes is configured to emit light of a second wavelength, the second wavelength being different than the first wavelength"

Claim 27 of the '745 patent depends from claim 20, further requiring that "at least one of the plurality of light-emitting diodes is configured to emit light of a first wavelength and at least one of the plurality of light-emitting diodes is configured to emit light of a second wavelength, the second wavelength being different than the first wavelength." There is no dispute that the Accused Products contain green (525 nm), red (660 nm), and infrared (850 nm) LEDs. *See* CIB at 202; Tr. (Madisetti) at 740:25-741:14; CDX-0011C.087 (citing CX-0059C (Apple Watch Series 7 drawing) at 2; CX-0057C (Apple Watch Series drawing) at 2; CX-0297C (Venugopal Dep. Tr.) at 53:1-55:14). The evidence of record shows that this limitation is met.

Accordingly, the evidence does not show direct infringement of claim 27 because Complainants have not proven, by a preponderance, that the Accused Products have a material that is configured to change emitted light from a "first shape" into a "second shape," as required by claim 20 (from which claim 27 depends).

3. Induced Infringement

Complainants contend that Apple induces infringement of '745 patent claim 27 by importing the Accused Products to be used in connection with Apple iPhones. CIB at 199-200.

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Complainants submit that Apple had knowledge of the '745 patent as of the filing of the original complaint on June 30, 2021. See CX-1254C (Apple interrogatory responses) at 35.

Complainants identify documentation from Apple instructing users how to connect the Accused Products with Apple iPhones. See CX-1727 (Apple Watch User Guide) at 1. Dr. Madisetti identified documentation from Apple instructing users how to pair an Apple Watch with an iPhone and use the Health app to monitor blood oxygen on the iPhone. Tr. (Madisetti) at 738:25-740:5; CDX-0011C.085 (citing CX-1727 (Apple Watch User Guide) at 1; CX-0010 (Apple website) at 2-3; CX-0299C (Waydo Dep. Tr.) at 74:11-75:17).

Apple argues that Complainants failed to carry their burden to show that Apple had the necessary specific intent for induced infringement. RRB at 88. Apple argues that that there is no testimonial evidence that Apple actively induced its users to infringe or that Apple knew that its users' actions would constitute infringement. *Id*.

In consideration of the parties' arguments, the undersigned finds that a preponderance of the evidence supports a finding that Apple knew of the alleged infringement of claim 27 as of the filing of the Complaint, which contained allegations of infringement (including a claim chart for claim 27) similar to the evidence presented at the hearing. *See* Complaint Exhibit 18 (June 30, 2021). In addition, there is no dispute that Apple has provided instructions to its users for pairing the Accused Products with Apple iPhones to monitor blood oxygen through Apple's Health app. *See* CX-1727 (Apple Watch User Guide) at 1; CX-0010 (Apple website) at 2-3; CX-0299C (Waydo Dep. Tr.) at 74:11-75:17. The Commission has found induced infringement based on similar evidence when there has been an underlying finding of direct infringement. *See, e.g., Certain Beverage Brewing Capsules*, Inv. No. 337-TA-929, Comm'n Op. at 17-21, EDIS Doc. ID 577827 (Apr. 5, 2016).

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The undersigned finds that Apple has not induced infringement of claim 27, however, because Complainants have not shown underlying direct infringement of this claim.

F. Domestic Industry—Technical Prong

The domestic industry products that Complainants rely on for the '745 patent are the Circle sensor (CPX-0021C) and the Wings sensor (CPX-0029C), the RevA sensor (CPX-0058C), and the RevE sensors (CPX-0019C, CPX-0020C, CPX-0065C) (collectively, "the '745 DI Products"). CIB at 203. Complainants allege that each of the '745 DI Products practices '745 patent claim 18, which depends from claim 15. *Id.* at 203-11.

1. '745 Patent Claim 18

a. Element [15 preamble]: "A physiological monitoring device comprising:"

There is no specific dispute that each of the '745 DI Products is a "physiological monitoring device" as required by the preamble of claim 15. *See* CIB at 204; RIB at 175-77. Mr. Scruggs testified that each of the '745 DI Products "supported the ability to measure oxygen saturation and pulse rate." Tr. (Suggs) at 393:17-20. Dr. Madisetti also observed a demonstration by Dr. Scruggs of the RevA, RevD, and RevE devices measuring oxygen saturation. Tr. (Madisetti) at 749:23-750:11. Dr. Madisetti also relied on a demonstration by Mr. Scruggs of the Circle and Wings sensors connected to a Rad-97 monitor. *Id.* at 754:24-

⁷⁵ Complainants assert that the Circle sensor and Wings sensor practice the '745 patent when connected to a Rad-97 monitor (CPX-0014a). CIB at 203, 209-10.

⁷⁶ Complainants also rely on the Masimo W1 as a domestic industry product, but for the reasons discussed *supra* in the context of the Poeze patents, evidence regarding this product will not be considered.

⁷⁷ Apple disputes whether certain of the '745 DI Products were operable before the filing of the Complaint, *see* RIB at 174-75, and this issue is addressed *infra*, Section VII.

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755:3. For these reasons and those discussed below with regard to Element [15H], the evidence of record shows that this limitation is met.

b. Element [15A]: "a plurality of light-emitting diodes configured to emit light proximate a wrist of a user"

There is no dispute that each of the '745 DI Products has a plurality of light-emitting diodes. *See* CIB at 204. Dr. Madisetti identified the LEDs in each of the '745 DI Products. Tr. (Madisetti) at 750:22-751:11; CDX-0011C.098. Mr. Scruggs testified that the '745 DI Products each contain LEDs. Tr. (Scruggs) at 393:12-394:3. The evidence of record shows that this limitation is met.

c. Element [15B]: "a light diffusing material configured to be positioned between the plurality of light-emitting diodes and a tissue measurement site on the wrist of the user when the physiological monitoring device is in use"

Mr. Scruggs identified "a diffusing media above the LEDs" in the '745 DI Products, which is for the Circle, Wings, RevA, RevD, and RevE sensors. Tr. (Scruggs) at 401:2-13. Dr. Madisetti observed the "diffusing the light" in a demonstration by Mr. Scruggs. Tr. (Madisetti) at 760:18-22; see also RX-0266C (demonstration of RevA sensor); RX-0267C (demonstration of RevD sensor); RX-0268C (demonstration of RevE sensor). Dr. Madisetti identified the location of the diffusing material in each of the '745 DI Products. Tr. (Madisetti) at 751:12-752:2; CDX-011C.099 (citing CX-1132C (Circle CAD) at 2; CX-0656C (Circle photo); CX-1137C (Wings CAD) at 6; CX-0658C (Wings photo); CX-111C (RevA CAD); CX-0661C (RevA photo); CX-1058C (RevD photo) at 442; CX-0666C (RevD photo); CX-1125C (RevE CAD) at 2; CX-0653C (RevE photo); CX-0655C (RevE photo); CX-0676C (RevE photo); CX-1058C (RevE photo) at 593). Complainants

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further submit that this material is located on the side of the product that contacts the user's wrist in each of the '745 DI Products, thus meeting this limitation. CIB at 205-07.

Apple argues that Dr. Madisetti's analysis of photos and images is insufficient to prove that the material above the LEDs in the '745 DI Products is a "light diffusing material." RIB at 175-76. Dr. Sarrafzadeh called this analysis "unscientific" and "unreliable given that the components are actually quite small." Tr. (Sarrafzadeh) at 1127:1-1128:4; RDX-7C.0162. Dr. Sarrafzadeh further testified that is not always a diffusing material." Tr. (Sarrafzadeh) at 1127:15-1128:8. Apple further argues that the documentation for the '745 DI Products is unreliable because of certain discrepancies between the physical exhibits and Masimo's schematics. RIB at 175.

In consideration of the parties' arguments, the undersigned finds that Complainants have shown, by a preponderance of the evidence, that the '745 DI Products have a "light diffusing material" meeting this limitation. Mr. Scruggs described the diffusing material in each of the '745 DI Products, noting the "milky color" above the LEDs. Tr. (Scruggs) at 401:2-13. He specifically identified the material in the Circle, Wings, RevA, RevD, and RevE sensors. *Id*.Dr. Madisetti confirmed the location of the material identified by Mr. Scruggs in photos and schematics of each of the '745 DI Products. Tr. (Madisetti) at 751:12-752:2.

Dr. Sarrafzadeh raises some questions regarding the reliability of Dr. Madisetti's analysis, but the appearance of the '745 DI Products in videos and photographs is consistent with Mr. Scruggs's testimony. *See* CDX-011C.099. On this record, a preponderance of the evidence supports a finding that each of the '745 DI Products meets this claim limitation with a light diffusing material positioned between the LEDs and the user's wrist.

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d. Element [15C]: "a light block having a circular shape"

There is no dispute that each of the '745 DI Products has a light block that forms a circular shape around the LEDs. *See* CIB at 207. Dr. Madisetti identified the circular light block photographs and schematics of each of the '745 DI Products. Tr. (Madisetti) at 752:3-10; CDX-0011C.100. Mr. Scruggs described a "light barrier . . . that surrounds the emitters so it separates the LEDs from the photodiodes." Tr. (Scruggs) at 400:9-12. The evidence of record shows that this limitation is met.

e. Element [15D]: "a plurality of photodiodes configured to detect at least a portion of the light emitted from the plurality of light-emitting diodes after the light passes through the light diffusing material and a portion of the tissue measurement site encircled by the light block, wherein the plurality of photodiodes are arranged in an array having a spatial configuration corresponding to a shape of the portion of the tissue measurement site encircled by the light block"

There is no dispute that each of the '745 DI Products has photodiodes that are arranged in a circular array around the light block that are configured to detect light that is reflected from the user's skin. *See* CIB at 207-08. Dr. Madisetti identified the arrangement of photodiodes in photographs and schematics of each of the '745 DI Products. Tr. (Madisetti) at 752:22-754:8; CDX-0011C.101. The evidence of record shows that this limitation is met.

f. Element [15E]: "wherein the plurality of photodiodes are further configured to output at least one signal responsive to the detected light"

There is no specific dispute that the photodiodes in each of the '745 DI Products are configured to output a signal responsive to detected light. *See* CIB at 208; RIB at 175-77. Dr. Madisetti identified circuit diagrams showing the output of the photodiodes in the RevA, RevD, and RevE devices. Tr. (Madisetti) at 754:9-755:6; CDX-0011C.102 (citing CX-0701C (RevA diagram) at 2, 6; CX-0710C (Rev D diagram) at 3, 7; CX-0705C (RevE diagram). With

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respect to the Circle and Wings sensors, Dr. Madisetti relied on a demonstration by Mr. Scruggs showing these sensors outputting oxygen saturation information to a separate Rad-97 monitor. Tr. (Madisetti) at 754:24-755:3. Mr. Scruggs explained that "the signal from the photodiodes was transmitted through a cable to the Rad-97 instrument." Tr. (Scruggs) at 403:18-404:2 (describing Circle sensor), 404:14-19 (describing Wings sensor). For these reasons, and those discussed in relation to Element [15H], the evidence of record shows that this limitation is met.

g. Element [15F]: "wherein the plurality of light-emitting diodes and the plurality of photodiodes are arranged in a reflectance measurement configuration"

There is no dispute that the photodiodes in each of the '745 DI Products are located on the same side as the LEDs and are thus arranged to detect light that is reflected from the user's wrist. *See* CIB at 209; Tr. (Madisetti) at 755:7-25; CDX-0011C.103. The evidence of record shows that this limitation is met.

h. Element [15G]: "wherein the light block is configured to optically isolate the plurality of light-emitting diodes from the plurality of photodiodes by preventing at least a portion of light emitted from the plurality of light-emitting diodes from reaching the plurality of photodiodes without first reaching the portion of the tissue measurement site"

There is no dispute that the light block in each of the '745 DI Products separates the LEDs from the photodiodes, blocking at least a portion of light from reaching the photodiodes without first reaching the user's skin. *See* CIB at 209; Tr. (Madisetti) at 756:1-15; CDX-0011C.104. The evidence of record shows that this limitation is met.

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i. Element [15H]: "a processor configured to receive and process the outputted at least one signal and determine a physiological parameter of the user responsive to the outputted at least one signal"

Dr. Madisetti identified processors for each of the '745 DI Products that receive and process signals from the photodiodes. Tr. (Madisetti) at 756:16-757:13; CDX-0011C.105. For the Circle sensor and Wings sensor, Mr. Scruggs explained that the relevant processor is in the Rad-97 instrument, which is connected to the sensors via a cable. Tr. (Scruggs) at 403:11-404:2 ("So the Circle sensor gathered the raw physiological data from the wrist using the LEDs and detectors, and the signal from the photodiodes was transmitted through a cable to the Rad-97 instrument. And then the Rad-97 instrument uses its processors, and the Masimo SET pulse oximetry algorithm to calculate oxygen saturation and pulse rate."), 405:1-7 (same for Wings sensor). Dr. Madisetti also relied on a demonstration by Mr. Scruggs of the Circle and Wings sensors connected to a Rad-97 monitor. Id. at 754:24-755:3. Dr. Madisetti also observed a separate demonstration by Dr. Scruggs of the RevA, RevD, and RevE devices measuring oxygen saturation. Tr. (Madisetti) at 749:23-750:11. Mr. Al-Ali described internal testing of the oxygen saturation measurements of Masimo sensors at the time of the RevA sensors. Tr. (Al-Ali) at 271:16-277:13; CX-0378C at 32. He also described testing relevant to the RevD sensors and the RevE sensors. Tr. (Al-Ali) at 276:12-278:3, 316:2-317:20; CX-0494C. Complainants submit that this evidence shows that each of the '745 DI Products has a processor that receives and processes signals from the photodiodes to calculate oxygen saturation. CIB at 209-11; CRB at 121.

Apple argues that the evidence in the record is insufficient to show that any of the '745 DI Products calculates oxygen saturation. RIB at 176-77. As discussed above in the context of the Poeze patents, Apple submits that Complainants failed to identify the source code in the

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domestic industry products that calculates any physiological parameter. *Id.* at 47-48; *see* Tr. (Sarrafzadeh) at 1124:24-1125:11. Dr. Sarrafzadeh offered his opinion that the evidence presented by Complainants was insufficient to determine whether the '745 DI Products calculated oxygen saturation. Tr. (Sarrafzadeh) at 1122:20-1126:20. He specifically highlights an erroneous oxygen saturation reading of "81" during a demonstration of the Wings sensor. *Id.* at 1124:12-23. With respect to the Circle sensor and Wings sensor, Apple argues that the claim limitation is not satisfied because the identified "processor" is not in the sensor but in the separate Rad-97 instrument. RIB at 177; RRB at 91.

In consideration of the parties' arguments, the undersigned finds that Complainants have shown by a preponderance of the evidence that each of the '745 DI Products has a processor that receives signals from the photodiodes and determines an oxygen saturation measurement. With respect to the Circle sensor and Wings sensor, claim 15 does not preclude the "physiological-monitoring device" from comprising a sensor that is connected to a separate instrument via a cable. As discussed above in the context of the Poeze patents, the testimony of Mr. Scruggs and Mr. Al-Ali regarding the design, testing, and operation of Masimo's products is sufficient to show that the '745 DI Products measure oxygen saturation. The demonstrations of the '745 DI Products during discovery further confirm the operation of these products, and the minor inconsistencies identified by Dr. Sarrafzadeh do not refute Complainants' affirmative evidence that these products measure oxygen saturation.

Accordingly, the evidence shows by a preponderance that each of the '745 DI Products has a processor that receives signals from the photodiodes and determines an oxygen saturation measurement.

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j. Element [15I]: "wherein the physiological monitoring device is configured to transmit physiological parameter data to a separate processor"

There is no specific dispute that the '745 DI Products are configured to transmit oxygen saturation data to an additional processor. See CIB at 211; RIB at 175-77. For the Circle and Wings sensors, Dr. Madisetti identified Wi-Fi and Bluetooth functionality in the Rad-97 instrument that would facilitate transmission of oxygen saturation data. Tr. (Madisetti) at 758:8-11; CDX-0011C.107 (citing CX-0679 at 96, 99). For the RevA sensor, Dr. Madisetti identified a laptop that received oxygen saturation data during a demonstration by Mr. Scruggs. Tr. (Madisetti) at 757:16-23; CDX-0011C.106 (citing CX-0836C (demonstration photos) at 4). Dr. Madisetti identified two separate processors in the RevD and RevE sensors, explaining that oxygen saturation data is sent from the processor to the processor. Tr. (Madisetti) at 757:14-758:6; CDX-0011C.106 (citing CX-0709C (RevD schematic) at 3). For the RevE sensor, Dr. Madisetti further identifies a phone that received oxygen saturation during a demonstration by Mr. Scruggs. Tr. (Madisetti) at 757:24-758:4; CDX-0011C.106 (citing CX-0836C (demonstration photos) at 8-13). For these reasons, and those discussed in relation to Element [15H], the evidence of record shows that this limitation is met by the '745 DI Products.

k. Element [18]: "wherein the physiological parameter comprises oxygen saturation"

Claim 18 of the '745 patent depends from claim 15, "wherein the physiological parameter comprises oxygen saturation." As discussed above in the context of the "processor" limitation, the undersigned finds that the '745 DI Products measure oxygen saturation.

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Accordingly, because each limitation of claims 15 and 18 are satisfied, the evidence shows, by a preponderance, that each of the '745 DI Products practice claim 18 of the '745 patent.

2. Status of DI Products at the Time of the Complaint

Apple argues that no patent-practicing domestic industry article existed at the time of the complaint. RIB at 174-75; RRB at 12-14. Complainants dispute Apple's contention. CRB at 119-20. Specifically, Apple disputes whether the Circle and Wings sensors were operable with the Rad-97 monitor before the complaint was filed. RIB at 174-75. Apple further disputes whether the RevA sensor was operable with a laptop before the complaint was filed. *Id*. Complainants rely on Mr. Scruggs's testimony that the Circle sensor, Wings sensor, RevA sensor, and RevD sensor were built before the complaint was filed. Tr. (Scruggs) at 394:12-397:24. Complainants further rely on Mr. Al-Ali's testimony regarding clinical testing of Masimo Watch devices. Tr. (Al-Ali) at 262:7-264:13, 268:22-278:13, 313:14-318:22.

Mr. Scruggs also testified that the Circle sensor was used in clinical studies at Masimo in October 2019. Tr. (Scruggs) at 475:8-15.

In consideration of the parties' arguments, the undersigned finds that at least the RevA, RevD, and RevE sensors were articles protected by the '745 patent that existed before the filing of the complaint. As discussed above in the context of the Poeze patents, the record evidence is sufficient to show that the RevA, RevD, and RevE devices existed prior to the filing of the complaint. Apple argues that the laptop Mr. Scruggs used to display the oxygen saturation measurement from the RevA sensor was not used with the RevA sensor before the filing of the complaint, RIB at 174, but this laptop is not part of the domestic industry article protected by claim 18 of the '745 patent. Mr. Scruggs's laptop was only used to demonstrate the final

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limitation of claim 15 [15I], which requires that the RevA sensor is "configured to transmit physiological parameter data to a separate processor." *See* Tr. (Madisetti) at 757:16-23; CX-0836C (demonstration photos) at 4. Mr. Scruggs's laptop was part of the demonstration showing that the RevA sensor was configured as required by the claims, but the laptop is not part of the domestic industry article—the RevA had the required configuration even in the absence of the laptop. With respect to the RevD and RevE sensors, Apple argues that software was loaded on these devices after the complaint was filed, RIB at 42-43, but as discussed above in the context of the Poeze patents, *supra* Section IV.F.7, the evidence shows that these devices were tested before the filing of the complaint. *See* Tr. (Al-Ali) at 276:17-278:13, 316:2-317:20 (citing CX-0494C). Moreover, at least one of the RevE devices produced in discovery (CPX-0019C) can be considered to represent devices that existed at the time of the complaint, based on software that is dated July 9, 2021.

With respect to the Circle sensor and the Wings sensor, the associated Rad-97 monitor is necessary to the practice of the "determine a physiological parameter" limitation [15H], and the protected domestic industry article thus comprises the sensors together with the Rad-97 monitor. Although Complainants have identified some evidence that the Circle and Wings sensors were used in testing in 2019 and 2020, there is no evidence that these sensors were used together with the identified Rad-97 monitor in those tests. *See* Tr. (Scruggs) at 475:8-15; Tr. (Al-Ali) at 262:7-263:10. Mr. Scruggs explained how the Circle and Wings sensor could have worked with the Rad-97, but he never confirmed that these sensors were used with a Rad-97 monitor at any time

⁷⁸ As described by Mr. Al-Ali, an October 2020 presentation describes internal testing of the oxygen saturation measurements of prototype sensors consistent with the RevA design. Tr. (Al-Ali) at 272:16-277:13; CX-0378C at 32.

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before the filing of the complaint. *See* Tr. (Scruggs) at 403:11-404:2 ("It could work with many of the Masimo instruments. One example of that would be the Rad-97."). Complainants have not shown that the asserted domestic industry articles—the Circle sensor connected to the Rad-97 monitor and the Wings sensor connected to the Rad-97 monitor—existed as articles protected by claim 18 of the '745 patent before the filing of the complaint.

Accordingly, Complainants have shown that at least with respect to the RevA, RevD, and RevE sensors, domestic industry articles protected by the '745 patent existed before the filing of the complaint, and Complainants have thus satisfied the technical prong for the '745 patent with respect to a domestic industry existing at the time of the complaint.

Moreover, for the same reasons discussed above in the context of the Poeze patents, supra Part IV.F.7-8, the evidence shows satisfaction of the technical prong for a domestic industry in the process of being established. In particular, the evidence shows, by a preponderance, that Masimo has taken the necessary tangible steps to develop a product that will practice claim 18 of the '745 patent and shows a significant likelihood that this product development will lead to a device that practices the claim.

G. Invalidity - Obviousness

Apple contends that claims 9 and 27 of the '745 patent are obvious in view of the Apple Watch Series 0 and that claims 9, 18, and 27 of the '745 patent are obvious in view of U.S. Patent No. 8,670,819 to Iwamiya *et al.* (RX-0130, "Iwamiya") in combination with U.S. Patent No. 9,392,946 to Sarantos *et al.* (RX-0366, "Sarantos") and U.S. Patent No. 8,998,815 to Venkatraman *et al.*, (RX-0368, "Venkatraman"). RIB at 178-201; RRB at 94-110. Complainants dispute Apple's allegations of obviousness, identifying certain objective indicia of non-obviousness in support of their arguments. CIB at 212-34; CRB at 121-33.

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1. Apple Watch Series 0

The Apple Watch Series 0 was the first commercial Apple Watch, and Apple submits that it went on sale to the public on April 24, 2015, citing an Apple press release and the testimony of Apple and Masimo witnesses. RX-0023 (Apple Press Release); Tr. (Block) at 910:22-911:2; Tr. (Kiani) at 138:1-4. Complainants dispute whether Apple has shown that the Apple Watch Series 0 was publicly available before the priority date of the '745 patent in July 2015. CIB at 212-13. Complainants argue that the press release only describes an expected release date and that Apple's witness testimony is uncorroborated. *Id.*; CRB at 123.

The record shows clear and convincing evidence that the Apple Watch Series 0 was publicly on sale by April 24, 2015. Apple's press release represents that the Apple Watch will be "Available for Purchase Online April 24." RX-0023. Complainants argue that the statement in this press release was made in advance of the release date, but the April 2015 release date for the Apple Watch Series 0 was further corroborated by the testimony of Dr. Block and Dr. Venugopal. Tr. (Block) at 910:22-24 ("It was released in the spring of 2015."); Tr. (Venugopal) at 818:10-15 ("The first customer ship for Series 0 was in April of 2015."). Complainants have identified no evidence that the announced release date for the Apple Watch Series 0 was delayed and no reason to doubt the testimony of Apple's witnesses—when Mr. Kiani was asked about his knowledge of the release of the first Apple Watch, he testified that "I don't remember the exact timing, but I'm sure those dates are correct." Tr. (Kiani) at 138:1-4. The evidence thus shows that the Apple Watch Series 0 was publicly available in April 2015, which qualifies it as prior art under 35 U.S.C. § 102(a)(1).

Complainants further argue that Apple has failed to introduce reliable evidence for the structure and operation of the Apple Watch Series 0, identifying several discrepancies between

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the product photos relied upon by Dr. Sarrafzadeh and the features described in Apple schematics. CIB at 213-18. The undersigned agrees with Apple, however, that the discrepancies identified by Complainants are irrelevant to the asserted claims of the '745 patent. *See* RRB at 95-97. The parties' disputes regarding the structure and operation of the Apple Watch Series 0 that are relevant to the limitations of the asserted claims are addressed below.

- a. '745 patent, claim 9
 - (i) Element [1 preamble]: "A physiological monitoring device comprising"

Apple contends that the Apple Watch Series 0 is a "physiological monitoring device" because it contains a heart rate sensor. RIB at 179; see Tr. (Sarrafzadeh) at 1092:7-13; Tr. (Waydo) at 937:2-8; Tr. (Land) at 957:5-15; RX-0396.0011C (Apple specification).

Complainants do not specifically dispute this preamble limitation. See CIB at 212-24; CRB at 122-27.

(ii) Element [1A]: "a plurality of light-emitting diodes configured to emit light in a first shape"

Apple contends that the Apple Watch Series 0 has four LEDs that emit light in a shape.

RIB at 179; see Tr. (Sarrafzadeh) at 1092:15-21; Tr. (Land) at 959:3-13; Tr. (Block) at 897:15-898:1. Dr. Venugopal testified that the Apple Watch Series 0 contained green and infrared LEDs, and the shape of the LEDs was square. Tr. (Venugopal) at 819:1-7, 820:16-821:11; RX-0392C.006 (Apple specification) at Fig. 2. Complainants do not specifically dispute this limitation. See CIB at 212-24; CRB at 122-27.

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(iii) Element [1B]: "a material configured to be positioned between the plurality of light-emitting diodes and tissue on a wrist of a user when the physiological monitoring device is in use, the material configured to change the first shape into a second shape by which the light emitted from one or more of the plurality of light-emitting diodes is projected towards the tissue"

Apple submits that the Apple Watch Series 0 has a "Fresnel lens" positioned between the LEDs and the user's wrist, which changes the shape of the light from the LEDs. RIB at 108-81. Dr. Venugopal identified the Fresnel lens as part of the Apple Watch Series 0. Tr. (Venugopal) at 819:1-7. Apple relies on an engineering requirement specification document for Apple's "Generation 1" optical sensing module, which was identified by Dr. Venugopal as applying to the Apple Watch Series 0 through 3. Id. at 820:10-15 (citing RX-0392C). Dr. Venugopal explained that "[t]he Fresnel lens had two purposes," which were "cosmetic obscuration" and "to have light emitted from the green LED to be collimated." Id. at 821:12-21. The green light is "positioned under the optical center," and "gets restricted to a certain angle so that most of it gets out of the window." Id. at 821:22-4, 822:22-25; RX-0392C.007 at Fig. 3. With respect to the infrared LED in the optical sensing module, Dr. Venugopal explained that "because it is not passing through an optical center, gets thrown off in a different direction, and it exits the watch and hits the skin a little bit further away." Tr. (Venugopal) at 823:4-9. He testified that the infrared light "has a crescent shape." Id. Dr. Sarrafzadeh relied on the Apple specification document and offered his opinion that the "Fresnel lens has these grooves as highlighted here, and these grooves take the shape of the LED and transform that into a crescent type of a shape." Tr. (Sarrafzadeh) at 1092:23-1093:8 (citing RX-0392C); see RDX-7.86C, RDX-7.87C.

Complainants argue that the testimony of Dr. Venugopal and Dr. Sarrafzadeh are insufficient to show that the Apple Watch Series 0 meets this limitation by clear and convincing

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evidence. CIB at 220-22. Complainants contend that there are no documents or testing to corroborate Apple's contention that the Fresnel lens changes the shape of the infrared light in the Apple Watch Series 0. *Id.* Complainants further cite an Apple patent (naming Dr. Venugopal among the inventors) describing a Fresnel lens whose effect is for a "light emitter to retain its optical power, collection efficiency, beam shape, and collection area such that the light undergoes minimal change." CX-1806 at ¶ 53.

Apple argues in reply that Dr. Sarrafzadeh's opinions are corroborated by the placement of the infrared LED in relation to the Fresnel lens shown in Apple's engineering documents, highlighting a close-up of the lens and the placement of the LEDs. RRB at 99-100.



RX-0392C.00 at Fig. 2. Apple submits that Dr. Sarrafzadeh and Dr. Venugopal explained how the offset placement of the infrared LED causes a change in shape as the light passes through a crescent-shaped portion of the Fresnel lens. *See* Tr. (Sarrafzadeh) at 1093:4-8; Tr. (Venugopal) at 823:4-9.

In consideration of the parties' arguments, the undersigned finds that Apple has failed to offer clear and convincing evidence that the Fresnel lens changes the shape of the light emitted by the infrared LED in the Apple Watch Series 0. Dr. Sarrafzadeh's testimony is conclusory—

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he asserts that the grooves on the Fresnel lens transforms the light "into a crescent type of a shape," but he merely showed a demonstrative with a drawing of a crescent that was not shown to be the result of any testing or observation of the Apple Watch Series 0. Tr. (Sarrafzadeh) at 1093:4-8; RDX-7.87C; Tr. (Madisetti) at 1358:3-5. Dr. Venugopal explained how the Fresnel lens collimates the green light at the optical center while throwing off the infrared light in a different direction because it is off-center, but he only offers a short conclusory statement about the shape of the infrared light: "It has a crescent shape." Tr. (Venugopal) at 821:22-823:9. Changing the shape of the infrared light is not one of the two purposes that Dr. Venugopal described for the Fresnel lens. See id. at 821:12-21.79 The record contains no images of the light passing through the Fresnel lens or any explanation for why Apple would have designed the Fresnel lens to change the shape of the infrared light, and the conclusory testimony of Dr. Sarrafzadeh and Dr. Venugopal falls short of the clear and convincing standard necessary to prove invalidity. See Motorola Mobility, LLC v. Int'l Trade Comm'n, 737 F.3d 1345, 1349 (Fed. Cir. 2013) (where expert's testimony was "a single sentence, without explanation," finding that the ALJ and Commission did not "act unreasonably in finding this conclusory sentence did not rise to the level of clear and convincing evidence").

> (iv) Element [1C]: "a plurality of photodiodes configured to detect at least a portion of the light after the at least the portion of the light passes through the tissue, the plurality of photodiodes further configured to output at least one signal responsive to the detected light"

Apple contends that the Apple Watch Series 0 has two photodiodes that detect light after it interacts with the user's tissue. RIB at 181; see Tr. (Sarrafzadeh) at 1093:9-12; Tr. (Land) at

⁷⁹ The Apple patent application cited by Complainants is consistent with Dr. Venugopal's testimony that the purpose of the Fresnel lens is to obscure internal components and to retain optical power. *See* CX-1806 at ¶ 53.

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959:3-13; Tr. (Venugopal) at 819:1-7; RX-0392C.006 at Fig. 2. Complainants do not specifically dispute this limitation. *See* CIB at 212-24; CRB at 122-27.

(v) Element [1D]: "a surface comprising a dark-colored coating, the surface configured to be positioned between the plurality of photodiodes and the tissue when the physiological monitoring device is in use, wherein an opening defined in the darkcolored coating is configured to allow at least a portion of light reflected from the tissue to pass through the surface"

Apple submits that the Apple Watch Series 0 has a back crystal, which is positioned between the photodiodes and the user's wrist and has openings to allow light reflected from the tissue to reach the photodiodes. RIB at 181-82; RRB at 101; see Tr. (Sarrafzadeh) at 1093:13-21; Tr. (Land) at 959:3-13. Dr. Sarrafzadeh testified that "the first layer of the is a dark-colored coating." Tr. (Sarrafzadeh) at 1093:13-21; RDX-7.89C. In the alternative, he offered his opinion that "one of ordinary skill knows that you can easily and low-tech add dark-colored coating to it." Id. Apple argues that dark-colored coatings were well-known in the prior art and would have been obvious to a person of ordinary skill in the art. RRB at 101 (citing RX-0366 (Sarantos) at 17:12-16; RX-0035.0202 (Webster)). Complainants dispute Apple's contentions, arguing that there is no evidence that the surface of the Apple Watch Series 0 has layers and that Dr. Sarrafzadeh's testimony is insufficient to establish that adding a dark-colored coating would have been obvious. CIB at 222-23.

In consideration of the parties' arguments, the undersigned agrees with Complainants that Apple has failed to show, clearly and convincingly, that the back crystal of the Apple Watch Series 0 is a "coating." There is no evidence that the

⁸⁰ Complainants note that the image on RDX-7.89C is an Apple Watch Series 1, not an Apple Watch Series 0. *See* CIB at 215.

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comprises layers that can be described as a "coating," and Apple has failed to offer clear and convincing evidence that one of ordinary skill in the art would have added a dark-colored coating to the surface of the back crystal in the Apple Watch Series 0. *See, e.g.*, JX-0009 at 9:32-34 (referring to a "top surface coated with a light-absorbing material"). Dr. Sarrafzadeh offers conclusory testimony that a person of ordinary skill in the art would have been able to add a "low-tech" coating to the Apple Watch Series 0, but even if this opinion were reliable, Dr. Sarrafzadeh fails to identify any reason to add such a coating. Such testimony is insufficient to carry Apple's burden to prove obviousness by clear and convincing evidence. *See InTouch Techs., Inc. v. VGO Commc'ns, Inc.*, 751 F.3d 1327, 1352 (Fed. Cir. 2014) (reversing obviousness finding where expert's "testimony primarily consisted of conclusory references to her belief that one of ordinary skill in the art could combine these references, not that they would have been motivated to do so.").

(vi) Element [1E]: "a light block configured to prevent at least a portion of the light emitted from the plurality of light-emitting diodes from reaching the plurality of photodiodes without first reaching the tissue"

With respect to the "light block" limitation, Apple relies on an Apple specification that depicts blocks labeled "light between the emitters and detectors.

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RX-0396C.0017 at Fig. 6.

." Tr. (Land)

at 961:22-962:13; see also Tr. (Sarrafzadeh) at 1093:22-1094:3. Complainants argue that the Apple specification cited by Mr. Land is unreliable, because it is dated July 2013—two years before the release of the Apple Watch Series 0—and it does not show the convex back surface that is in the final product. CIB at 216-17; CRB at 127; see Tr. (Madisetti) at 1356:10-22.

In consideration of the parties' arguments, the undersigned finds that Apple has shown by clear and convincing evidence that the Apple Watch Series 0 meets the "light block" limitation of the '745 patent claim 1. Mr. Land identified the Apple engineering requirement specification document as one that corresponds to the Apple Watch Series 0. Tr. (Land) at 961:7-21 (identifying RX-0396C). He described the optical path diagram in that document as "a schematic for some of the major elements in the Apple Watch." *Id.* at 961:22-962:13. The fact

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that the diagram does not show other features of the Apple Watch, such as the curved back crystal, is irrelevant to this limitation. Mr. Land's testimony and the diagram from Apple's specification clearly show that the Apple Watch Series 0 had the claimed "light block."

(vii) Element [1F]: "a processor configured to receive and process the outputted at least one signal and determine a physiological parameter of the user responsive to the outputted at least one signal"

Apple contends that the Apple Watch Series 0 has a processor that receives signals from the photodiodes and calculates a pulse rate. RIB at 183; see Tr. (Sarrafzadeh) at 1094:4-9; Tr. (Land) at 959:3-13; RX-0392C.011. Complainants do not specifically dispute this limitation. See CIB at 212-24; CRB at 122-27.

(viii) Element [9]: "wherein the physiological parameter comprises oxygen saturation"

Claim 9 of the '745 patent depends from claim 1, "wherein the physiological parameter comprises oxygen saturation." The Apple Watch Series 0 does not measure oxygen saturation, but Dr. Sarrafzadeh offered his opinion that pulse oximetry would have been obvious to a person of ordinary skill in the art because such devices have been known since the 1970s. Tr. (Sarrafzadeh) at 1094:10-17. Apple cites testimony from Dr. Mehra that "pulse oximetry as a feature is essentially heart rate sensing, but comparing the amplitude of the signal at two different colors of light or wavelengths of light." Tr. (Mehra) at 852:7-17. Dr. Waydo testified that Apple's later development of a blood oxygen sensor built on its work on heart rate detection, because "the blood oxygen sensor is a PPG of photoplethysmography sensor, much like the heart rate sensors." Tr. (Waydo) at 923:12-23. Dr. Mannheimer testified that "putting a couple of LEDs in a Series 0 watch form factor" would produce a blood oxygen measurement, "but not to the level that we were looking for." Tr. (Mannheimer) at 1015:9-19.

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Complainants argue that Apple failed to identify what modifications to the Apple Watch Series 0 would be necessary to measure oxygen saturation. CIB at 218-20. Complainants further identify evidence that Apple engineers expressed skepticism regarding Apple's likelihood of success in implementing an oxygen saturation measurement in the Apple Watch. *See* Tr. (Mannheimer) at 1012:12-16; CX-0299C (Waydo Dep. Tr.) at 166:4-167:5; CX-0295C (Shui Dep. Tr.) at 108:15-21. Complainants argue that it is unlikely that one of ordinary skill in the art would have been successful in modifying the Apple Watch Series 0 to measure oxygen saturation when the record shows that Apple's team of engineers worked for several years after the Apple Watch's release to implement this feature. CIB at 220.

In consideration of the parties' arguments, the undersigned finds that Apple has failed to offer clear and convincing evidence that one of ordinary skill in the art would have modified the Apple Watch Series 0 to measure oxygen saturation with a reasonable expectation of success. Apple cites the testimony of its engineers that adding some LEDs would make it possible to measure oxygen saturation, but there is no clear explanation of the modifications that would be necessary. *See* Tr. (Mannheimer) at 1015:9-19. The Federal Circuit has found such generalized arguments for combining prior art features to be insufficient, holding that it may be necessary to provide "a clear, evidence-supported account of the contemplated workings of the combination" as "a prerequisite to adequately explaining and supporting a conclusion that a relevant skilled artisan would have been motivated to make the combination and reasonably expect success in doing so." *Personal Web Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 994 (Fed. Cir. 2017). Here, Apple has failed to explain how the addition of LEDs for measuring blood oxygen would have been implemented, and whether these modifications would affect other limitations of the '745

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patent—such as the Fresnel lens that Apple relies on for the "second shape" limitation. ⁸¹ In addition, the record contains testimony from multiple Apple engineers expressing skepticism regarding the implementation of pulse oximetry in the Apple Watch. *See* Tr. (Mannheimer) at 1012:12-16; CX-0299C (Waydo Dep. Tr.) at 166:4-167:5; CX-0295C (Shui Dep. Tr.) at 108:15-21. Apple has thus failed to show how one of ordinary skill in the art would have modified the Apple Watch Series 0 to measure blood oxygen and has failed to show, clearly and convincingly, that that there would have been a reasonable expectation of success in making any such modifications.

Accordingly, the evidence fails to show that claim 9 of the '745 patent is obvious in view of the Apple Watch Series 0, because Apple has not clearly and convincingly shown that the Apple Watch Series 0 has a material that changes emitted light from a "first shape" to a "second shape," or that it would have been obvious for one of ordinary skill in the art to modify the Apple Watch Series 0 to have a "dark-colored coating" or to measure oxygen saturation.

b. '745 Patent Claim 27

(i) Element [20 preamble]: "A system configured to measure one or more physiological parameters of a user"

The preamble of claim 20 of the '745 patent requires "[a] system configured to measure one or more physiological parameters of a user," including "a physiological monitoring device." As discussed above in the context of the preamble of '745 patent claim 1, there is no dispute that the Apple Watch Series 0 is a "physiological monitoring device" because it contains a heart rate sensor. *See* RIB at 184.

⁸¹ When Apple implemented a blood oxygen feature in the Apple Watch Series 6, the Fresnel lens was removed in favor of a microlens array. *See* Tr. (Venugopal) at 836:3-838:25.

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(ii) Element [20A]: "a plurality of light-emitting diodes configured to emit light in a first shape"

Claim 20 has a "plurality of light-emitting diodes" limitation that is identical to the limitation of claim 1. As discussed above in the context of claim 1, there is no dispute that the Apple Watch Series 0 has four LEDs that emit light in a shape. *See* RIB at 179, 185.

(iii) Element [20B]: "a material configured to be positioned between the plurality of light-emitting diodes and tissue of the user when the physiological monitoring device is in use, the material configured to change the first shape into a second shape by which the light emitted from one or more of the plurality of light-emitting diodes is projected towards the tissue"

Claim 20 has a "material configured to change the first shape into a second shape" limitation that is identical to the limitation of claim 1. For the reasons discussed above in the context of claim 1, the undersigned finds that Apple has not shown that the Apple Watch Series 0 has a material that changes a "first shape" into a "second shape."

(iv) Element [20C]: "a plurality of photodiodes configured to detect at least a portion of the light after the at least the portion of the light passes through the tissue, the plurality of photodiodes further configured to output at least one signal responsive to the detected light"

Claim 20 has a "plurality of photodiodes" limitation that is identical to the limitation of claim 1. As discussed above in the context of claim 1, there is no dispute that the Apple Watch Series 0 has two photodiodes that detect light after it interacts with the user's tissue. *See* RIB at 181, 185.

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(v) Element [20D]: "a surface comprising a dark-colored coating, the surface configured to be positioned between the plurality of photodiodes and the tissue when the physiological monitoring device is in use, wherein an opening defined in the darkcolored coating is configured to allow at least a portion of light reflected from the tissue to pass through the surface"

Claim 20 has a "surface comprising a dark-colored coating" limitation that is identical to the limitation of claim 1. For the reasons discussed above in the context of claim 1, Apple has not shown that the Apple Watch Series 0 has a surface comprising a dark-colored coating or that one of ordinary skill in the art would have added such a coating.

(vi) Element [20E]: "a light block configured to prevent at least a portion of the light emitted from the plurality of light-emitting diodes from reaching the plurality of photodiodes without first reaching the tissue"

Claim 20 has a "light block" limitation that is identical to the limitation of claim 1. For the reasons discussed above in the context of claim 1, the evidence shows that the Apple Watch Series 0 has a light block that prevents at least a portion of light from the LEDs from reaching the photodiodes.

(vii) Element [20F]: "a processor configured to receive and process the outputted at least one signal and determine a physiological parameter of the user responsive to the outputted at least one signal"

Claim 20 has a "processor" limitation that is identical to the limitation of claim 1. As discussed above in the context of claim 1, there is no dispute that the Apple Watch Series 0 has a processor that receives signals from the photodiodes and calculates a pulse rate. *See* RIB at 183, 185.

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(viii) Element [20G]: "a processing device configured to wirelessly receive physiological parameter data from the physiological monitoring device, wherein the processing device comprises a user interface, a storage device, and a network interface configured to wirelessly communicate with the physiological monitoring device, and wherein the user interface includes a touch-screen display configured to present visual feedback responsive to the physiological parameter data"

Apple contends and provided testimony that the Apple Watch Series 0 wirelessly communicates with an Apple iPhone comprising a user interface including a touch-screen display, a storage device, and a wireless interface. RIB at 185; see Tr. (Sarrafzadeh) at 1095:17-1096:5. Complainants dispute whether Apple has shown that an iPhone could display the pulse rate measurement of an Apple Watch Series 0, however, arguing that Apple failed to identify any application on the iPhone for presenting any visual feedback responsive to any physiological parameter data. CIB at 223. En his testimony, Dr. Sarrafzadeh stated that the Apple Watch could wirelessly communicate with a cell phone such as an iPhone, and that "the app can provide a visual feedback to show the physiological parameters," thus showing that this limitation is met. See Tr. (Sarrafzadeh) at 1095:17-1096:5; RDX-7.94C. While Dr. Sarrafzadeh did not identify a particular app for these application, his testimony is unrebutted, and Apple's public statements at the time of the release of the Apple Watch Series 0 described "Apple Watch's health and fitness features" and offered customers assistance "to pair their Apple Watch with their iPhone." RX-0023.

⁸² Apple argues that this argument has been waived, RRB at 102, but Complainants' pre-hearing brief includes a contention that "Apple provides no evidence to show how an iPhone meets the elements within [20G]." CPHB at 164.

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(ix) Element [27]: "wherein at least one of the plurality of lightemitting diodes is configured to emit light of a first wavelength and at least one of the plurality of light-emitting diodes is configured to emit light of a second wavelength, the second wavelength being different than the first wavelength"

Claim 27 of the '745 patent depends from claim 20, further requiring that "at least one of the plurality of light-emitting diodes is configured to emit light of a first wavelength and at least one of the plurality of light-emitting diodes is configured to emit light of a second wavelength, the second wavelength being different than the first wavelength." Apple submits that the Apple Watch Series 0 has green and infrared LEDs. RIB at 185; *see* Tr. (Sarrafzadeh) at 1096:6-10; Tr. (Land) at 959:3-13; Tr. (Venugopal) at 819:1-7, 820:16-821:11; RX-0392C.006 (Apple specification) at Fig. 2. Complainants do not specifically dispute this limitation. *See* CIB at 212-24; CRB at 122-27.

For the reasons discussed above, the evidence of record fails to show that claim 27 of the '745 patent is obvious in view of the Apple Watch Series 0. Apple has not shown, clearly and convincingly, that the Apple Watch Series 0 has a material that changes emitted light from a "first shape" to a "second shape," and Apple has not shown, clearly and convincingly, that it would have been obvious to modify the Apple Watch Series 0 to have a "dark-colored coating" as required by the limitations of claim 20.

2. Iwamiya

U.S. Patent No. 8,670,819 is entitled "Optical Biological Information Detecting Apparatus and Optical Biological Information Detecting Method," naming inventors Hiroshi Iwamiya and Shuji Nakajima, and assignee Casio Computer Co. Ltd. RX-0130 ("Iwamiya"). Iwamiya issued on March 11, 2014, from an application filed on June 29, 2010, *id.*, and

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accordingly it is prior art to the '745 patent pursuant to 35 U.S.C. § 102(a)(1). Apple contends that claims 9, 18, and 27 of the '745 patent are obvious in view of Iwamiya in combination with other prior art patents. RIB at 186-99; RRB at 102-09.

- a. '745 Patent Claim 9
 - (i) Element [1 preamble]: "A physiological monitoring device comprising"

There is no dispute that Iwamiya discloses a "physiological monitoring device" because it discloses an "optical biological information detecting apparatus." RX-0130; *see* RIB at 186; Tr. (Sarrafzadeh) at 1098:8-12; Tr. (Madisetti) at 1359:8-1365:6.

(ii) Element [1A]: "a plurality of light-emitting diodes configured to emit light in a first shape"

There is no dispute that Iwamiya discloses light-emitting diodes emitting light in a shape. RX-0130 at 6:7-11, Fig. 4; *see* RIB at 186; Tr. (Sarrafzadeh) at 1098:13-18; RDX-7.100C; Tr. (Madisetti) at 1359:8-1365:6.

(iii) Element [1B]: "a material configured to be positioned between the plurality of light-emitting diodes and tissue on a wrist of a user when the physiological monitoring device is in use, the material configured to change the first shape into a second shape by which the light emitted from one or more of the plurality of light-emitting diodes is projected towards the tissue"

There is no dispute that Iwamiya discloses an "annular light guide unit" that is positioned between the light-emitting diodes and a user's wrist and changes the shape of the light into an annular shape. RX-0130 at 6:11:14 ("an annular guide unit 7 that guides the observation light emitted from the light emitting units 6 and annularly diffuses and irradiates the observation light with respect to a skin H"), 6:22-31 (describing location of light guide unit 7), see RIB at 186-87; Tr. (Sarrafzadeh) at 1098:19-1099:2; RDX-7.101C; Tr. (Madisetti) at 1359:8-1365:6.

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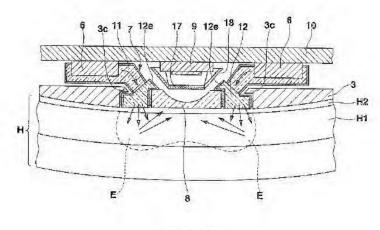


FIG.4

RX-0130 at Fig. 4.

(iv) Element [1C]: "a plurality of photodiodes configured to detect at least a portion of the light after the at least the portion of the light passes through the tissue, the plurality of photodiodes further configured to output at least one signal responsive to the detected light"

There is no dispute that Iwamiya discloses a plurality of photodiodes that output a signal responsive to light that is reflected from a user's tissue. RX-0130 at 8:20-23, Fig. 4; *see* RIB at 187-88; Tr. (Sarrafzadeh) at 1099:3-6, 1105:12-16; RDX-7.102C; Tr. (Madisetti) at 1359:8-1365:6.

(v) Element [1D]: "a surface comprising a dark-colored coating, the surface configured to be positioned between the plurality of photodiodes and the tissue when the physiological monitoring device is in use, wherein an opening defined in the darkcolored coating is configured to allow at least a portion of light reflected from the tissue to pass through the surface"

Apple identifies a "light shielding frame" that surrounds the photodiodes in Iwamiya, RX-0130 at 8:38-42, and Dr. Sarrafzadeh testifies that it would have been obvious to add a dark-colored coating to this surface, and one example of such a coating is disclosed in Sarantos. Tr.

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(Sarrafzadeh) at 1099:7-15; RDX-7.103C (citing RX-0366 at 17:6-16, Fig. 22). 83

Dr. Sarrafzadeh submits that both Iwamiya and Sarantos are wrist-worn physiological monitoring devices, and one of ordinary skill in the art would have been motivated to add a dark-colored coating to Iwamiya to enhance the light shielding. Tr. (Sarrafzadeh) at 1100:15-1101:4.

Dr. Sarrafzadeh testified that one of ordinary skill in the art would have expected success in implementing the "low-tech" and "low cost" addition of a dark-colored coating. *Id.* at 1101:5-10. Dr. Sarrafzadeh further cites Webster's disclosure that "black opaque material" can be an effective light shield. *Id.* at 1100:22-1101:4; RDX-7.109C; RX-0035 at 202.

Complainants argue that one of ordinary skill in the art would not have been motivated to add a dark-colored coating to Iwamiya because Iwamiya discloses "light shielding" that uses a reflective material. *See* Tr. (Madisetti) at 1361:9-12 (citing RX-0130 at 18:61-65). In reply, Apple argues that the reflective light shielding is disclosed in a separate embodiment of Iwamiya that is not relevant to the Figure 4 embodiment identified by Dr. Sarrafzadeh. RRB at 106-07.

In consideration of the parties' arguments, the undersigned finds that the evidence clearly and convincingly shows a reason to use a dark-colored coating for the "light shielding frame" in Figure 4. Dr. Sarrafzadeh convincingly explains that one of ordinary skill in the art would have reason to use a dark-colored coating, such as that disclosed in Sarantos, to improve the light-shielding properties of the Figure 4 embodiment, and that one of ordinary skill in the art would have expected success in implementing this change. While Iwamiya discloses a reflective light shielding component with respect to another embodiment (RX-0130 at 18:61-65), this does not

⁸³ Sarantos is U.S. Patent No. 9,392,946, which names inventors Chris W. Sarantos and Peter W. Richards, and issued from an application filed on May 28, 2015. RX-0366. Accordingly, Sarantos is prior art to the '745 patent pursuant to 35 U.S.C. § 102(a)(2).

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teach away from the use of other light shielding options or enhancements known in the art, particularly with respect to the Figure 4 embodiment, which does not mention "reflective" shielding. See, e.g., Syntex (U.S.A.) LLC v. Apotex, 407 F.3d 1371, 1379 (Fed. Cir. 2005) ("What a reference teaches a person of ordinary skill is not . . . limited to what a reference specifically 'talks about' . . . a reference will teach way when it suggests that the developments flowing from its disclosures are unlikely to produce the objective of the applicant's invention . . .").

(vi) Element [1E]: "a light block configured to prevent at least a portion of the light emitted from the plurality of light-emitting diodes from reaching the plurality of photodiodes without first reaching the tissue"

There is no dispute that Iwamiya discloses reflection layers 13 and 15 that are light blocks configured to prevent light from the light-emitting diodes from reaching the photodiodes without first reaching the tissue. RX-0130 at 6:67-7:3, 7:45-49, Fig. 3; see RIB at 189-90; Tr. (Sarrafzadeh) at 1099:16-21; RDX-7.104C; Tr. (Madisetti) at 1359:8-1365:6.

(vii) Element [1F]: "a processor configured to receive and process the outputted at least one signal and determine a physiological parameter of the user responsive to the outputted at least one signal"

There is no dispute that Iwamiya discloses a CPU that receives and processes signals from the photodiodes and "outputs the data as biological information" that represents a physiological parameter. RX-0130 at 9:40-43, Fig. 10; *see* RIB at 190-91; Tr. (Sarrafzadeh) at 1099:22-1100:1; RDX-7.105C; Tr. (Madisetti) at 1359:8-1365:6.

(viii) Element [9]: "wherein the physiological parameter comprises oxygen saturation"

Claim 9 of the '745 patent depends from claim 1, "wherein the physiological parameter comprises oxygen saturation." Dr. Sarrafzadeh testified that this limitation is obvious in view of

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Iwamiya's disclosure of a measurement of "biological information," because oxygen saturation is a type of biological information. Tr. (Sarrafzadeh) at 1100:2-8; RDX-7.106C; see RX-0130 at 9:1-7. Apple further submits that the prior art Sarantos reference explicitly discloses a measurement of oxygen saturation, explaining that "[i]f multiple light-emitting devices are used. . . photoplethysmographic techniques may also be used to measure other physiological parameters besides heart rate, such as blood oxygenation levels." RX-0366 at 13:44-47; see Tr. (Sarrafzadeh) at 1100:9-14. Dr. Sarrafzadeh offered his opinion that one of ordinary skill in the art would have been motivated to use the teaching in Sarantos to measure oxygen saturation in Iwamiya because both references describe wrist-worn physiological monitoring devices, and measuring oxygen saturation would enhance Iwamiya's device. Tr. (Sarrafzadeh) at 1100:15-20, 1101:12-19. Dr. Sarrafzadeh also offered his opinion that such a combination would be successful based on Sarantos's suggestion and the existence of oxygen saturation measurement devices in the prior art. Id. at 1101:20-1102:1.

Complainants argue that Iwamiya's disclosure of a measurement of "biological information" is insufficient to show a measurement of oxygen saturation. CIB at 225-26. Dr. Madisetti explained that Iwamiya only disclosed the use of one wavelength of light, which would be insufficient for measuring oxygen saturation. Tr. (Madisetti) at 1359:22-1361:1; CDX-0012C.065. Moreover, the only "biological information" disclosed in Iwamiya is heart rate. RX-0130 at 9:1-7 ("pulse wave"); see Tr. (Madisetti) at 1360:2-4. Complainants further identify an optical filter disclosed in Iwamiya that would block light below 900nm, which would preclude the wavelengths necessary for pulse oximetry. CIB at 227 (citing RX-0130 at 8:42-47, 18:55-60). Sarantos is also not primarily designed for the wavelengths necessary for pulse oximetry, noting that "[t]he aspect ratios and dimensional values discussed herein are tailored

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based on the green/yellow light spectrum and are not tailored for use in other spectrums, such as the red or infrared spectra." RX-0336 at 18:48-51. Complainants further argue that Apple has failed to identify a reason for combining Iwamiya and Sarantos or to show that such a combination would have a reasonable expectation of success. CIB at 228-30; CRB at 128-29.

In consideration of the parties' arguments, the undersigned finds that Apple has failed to show by clear and convincing evidence that it would have obvious for one of ordinary skill to combine Iwamiya and Sarantos to measure oxygen saturation. Because Iwamiya only discloses the use of one wavelength of light, the evidence indicates that one of ordinary skill in the art would not have been able to use the device in Iwamiya to measure oxygen saturation. Tr. (Madisetti) at 1359:22-1361:1. Moreover, Iwamiya operates at wavelengths that are not appropriate for pulse oximetry. See RX-0130 at 8:42-47; CIB at 227 (Iwamiya blocks light below 900 nm). Sarantos includes a suggestion to use multiple emitters with PPG sensors to measure blood oxygenation levels, but the only reason that Dr. Sarrafzadeh identifies for adding such a feature is that it "would enhance, by way of example, what the biological information of Iwamiya is." Tr. (Sarrafzadeh) at 1101:12-19. The Federal Circuit has held that such generic expert testimony is insufficient for obviousness. See ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc., 694 F.3d 1312, 1328 (Fed. Cir. 2012) (where expert testified that a motivation would have been "to build something better," the court found that "[t]his testimony is generic and bears no relation to any specific combination of prior art elements.").84

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⁸⁴ Moreover, Apple fails to explain how the multiple emitters described in Sarantos would have been implemented in Iwamiya in a way that is compatible with the annular light guide that is necessary to meet the "second shape" limitation. *See Personal Web Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 994 (Fed. Cir. 2017) (reversing a finding of obviousness where the record lacked "a clear, evidence-supported account of the contemplated workings of the combination").

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Apple also has not clearly and convincingly shown that one of ordinary skill in the art would have had a reasonable expectation of success in modifying Iwamiya to measure oxygen saturation—the record contains testimony from multiple Apple engineers expressing skepticism regarding the implementation of pulse oximetry in a wrist-worn device. *See* Tr. (Mannheimer) at 1012:12-16; CX-0299C (Waydo Dep. Tr.) at 166:4-167:5; CX-0295C (Shui Dep. Tr.) at 108:15-21.

Accordingly, Apple has failed to show that claim 9 of the '745 patent is obvious in view of Iwamiya in combination with Sarantos, because Apple has not shown, clearly and convincingly, that it would have been obvious to one of ordinary skill in the art to modify the device disclosed in Iwamiya with the teachings in Sarantos regarding a measurement of oxygen saturation with a reasonable expectation of success.

b. '745 Patent Claim 18

(i) Element [15 preamble]: "A physiological monitoring device comprising:"

There is no dispute that Iwamiya discloses a "physiological monitoring device" as required by the preamble of claim 15, as discussed above in the context of the preamble of claim 1. See RIB at 193.

(ii) Element [15A]: "a plurality of light-emitting diodes configured to emit light proximate a wrist of a user"

There is no dispute that Iwamiya discloses light emitting diodes, as discussed above in the context of claim 1. *See* RIB at 193. Moreover, there is no dispute that Iwamiya discloses a device that is worn on the wrist. *See* RX-0130 at 4:54-5, Fig. 4.

(iii) Element [15B]: "a light diffusing material configured to be positioned between the plurality of light-emitting diodes and a

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tissue measurement site on the wrist of the user when the physiological monitoring device is in use"

There is no dispute that Iwamiya discloses an "annular light guide" that "annularly diffuses and irradiates the observation light." RX-0130 at 6:10-14, Fig. 4; see Tr. (Sarrafzadeh) at 1103:10-15; RDX-7.116C. Moreover, there is no dispute that this annular light guide is positioned between the light-emitting diodes and the user's wrist, as discussed above in the context of claim 1. See RIB at 193.

(iv) Element [15C]: "a light block having a circular shape"

There is no dispute that Iwamiya discloses reflection layers 13 and 15 that are light blocks, as discussed above in the context of claim 1. *See* RIB at 193-94. Figures 2 and 3 of Iwamiya show that these light blocks are arranged around the annular light guide in a circular shape. RX-0130 at 6:67-7:3, 7:45-49, Fig. 2, Fig. 3; *see* Tr. (Sarrafzadeh) at 1103:16-21; RDX-7.117C.

(v) Element [15D]: "a plurality of photodiodes configured to detect at least a portion of the light emitted from the plurality of light-emitting diodes after the light passes through the light diffusing material and a portion of the tissue measurement site encircled by the light block, wherein the plurality of photodiodes are arranged in an array having a spatial configuration corresponding to a shape of the portion of the tissue measurement site encircled by the light block"

There is no dispute that Iwamiya discloses a plurality of photodiodes configured to detect light that is reflected from a user's tissue, as discussed above in the context of claim 1. See RIB at 194-95. Iwamiya further describes "the plural light receiving units 9 preferably disposed on the same circumference centered on an optical axis of the scattered light taking unit 8." RX-0130 at 14:39-41, Fig. 4; see Tr. (Sarrafzadeh) at 1103:22-1104:5; RDX-7.118C. Dr. Sarrafzadeh testified that he believes this limitation is indefinite but that "using Masimo's

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interpretation," this limitation is disclosed by Iwamiya. See Tr. (Sarrafzadeh) at 1103:23-5; RDX-7.118C.

Complainants argue that the disclosure in Iwamiya identified by Apple is insufficient to teach a plurality of photodiodes "arranged in an array having a spatial configuration corresponding to a shape of the portion of the tissue measurement site encircled by the light block." CIB at 232; CRB at 130-31. Complainants submit that Iwamiya only depicts a single light receiving unit. *See* Tr. (Madisetti) at 1364:7-8. Complainants further cite a statement in the prosecution history of a parent application to the '745 patent explaining that the plurality of detectors "must include sufficient detectors to represent such shapes." CX-1760 at 322; *see* Tr. (Madisetti) at 1366:13-1367:19.

In consideration of the parties' arguments, the undersigned finds that Iwamiya clearly discloses "plural light receiving units." *See* RX-0130 at 14:36-41; Tr. (Sarrafzadeh) at 1103:23-1104:5; RDX-7.118C (citing RX-0130 at 14:39-41). These plural light receiving units are further described as "disposed on the same circumference centered on an optical axis of the scattered light taking unit." *Id.* at 14:39-41; Tr. (Sarrafzadeh) at 1103:23-1104:5; RDX-7.118C. This disclosure of "plural" photodiodes that are "on the same circumference" at least renders the limitation requiring "a spatial configuration corresponding to a shape . . . encircled by the light block" to be *prima facie* obvious. *See* CRB at 131 (to meet [15D], "a plurality of photodiodes would need to be arranged in a circular-shaped array"). Iwamiya's "plural light receiving units" is a plurality, ⁸⁵ and the "same circumference" corresponds to a shape encircled by the light block. *See* RX-0130 at 14:36-41.

⁸⁵ Complainants cite statements in the prosecution history of a parent application to the '745 patent where the applicant suggested that up to six detectors may be needed to represent a circular shape. *See* CX-1760

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(vi) Element [15E]: "wherein the plurality of photodiodes are further configured to output at least one signal responsive to the detected light"

There is no dispute that the photodiodes in Iwamiya are configured to output a signal responsive to the detected light, as discussed above in the context of claim 1. See RIB at 195.

(vii) Element [15F]: "wherein the plurality of light-emitting diodes and the plurality of photodiodes are arranged in a reflectance measurement configuration"

There is no dispute that the light-emitting diodes in Iwamiya are arranged in a reflectance measurement configuration with the photodiodes on the same side of the tissue. *See* RIB at 195; Tr. (Sarrafzadeh) at 1104:11-15; RDX-7.119C; Tr. (Madisetti) at 1359:8-1365:6.

(viii) Element [15G]: "wherein the light block is configured to optically isolate the plurality of light-emitting diodes from the plurality of photodiodes by preventing at least a portion of light emitted from the plurality of light-emitting diodes from reaching the plurality of photodiodes without first reaching the portion of the tissue measurement site"

There is no dispute that the light blocks in Iwamiya are configured to prevent light from the light-emitting diodes from reaching the photodiodes without first reaching the tissue, as discussed above in the context of claim 1. *See* RIB at 195-96.

(ix) Element [15H]: "a processor configured to receive and process the outputted at least one signal and determine a physiological parameter of the user responsive to the outputted at least one signal"

There is no dispute that Iwamiya discloses a CPU that receives and processes signals from the photodiodes and determines a physiological parameter, as discussed above in the context of claim 1. See RIB at 196.

at 322. Both a "plural" and a "plurality" could include six photodiodes. *See In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003) ("In cases involving overlapping ranges, we and our predecessor courts have consistently held that even a slight overlap in range establishes a prima facie case of obviousness.").

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(x) Element [15I]: "wherein the physiological monitoring device is configured to transmit physiological parameter data to a separate processor"

Apple relies on Venkatraman in combination with Iwamiya for the limitation requiring that the physiological parameter can be transmitted to a separate processor. RIB at 196-97.86 Venkatraman discloses a biometric device that can communicate with a secondary device (e.g., a smartphone) through a wired or wireless connection. RX-0368 at 30:66-31:35. "The biometric monitoring device may send biometric and other data to the smartphone in real-time or with some delay." Id. at 57:44-46. Venkatraman describes numerous benefits to using a biometric device with a smartphone app. See id. at 57:20-59:13. Dr. Sarrafzadeh testified that it would have been obvious to one of ordinary skill in the art to combine Iwamiya's device with the secondary device of Venkatraman because such connections were well known to enhance such devices. Tr. (Sarrafzadeh) at 1105:24-1106:7, 1108:9-18. Dr. Sarrafzadeh also testified that a person of ordinary skill in the art would have had a reasonable expectation of success, "because adding these external devices was known for quite a bit of time." Id. at 1106:8-11, 1108:19-23. Complainants do not dispute that the evidence shows a reason to combine Iwamiya with Venkatraman, and a reasonable expectation of success, with regard to this limitation. See Tr. (Madisetti) at 1359:8-1365:6.

(xi) Element [18]: "wherein the physiological parameter comprises oxygen saturation"

Claim 18 of the '745 patent depends from claim 15, "wherein the physiological parameter comprises oxygen saturation." Apple submits that the measurement of oxygen saturation is

⁸⁶ Venkatraman is U.S. Patent No. 8,998,815, which names inventors Subramaniam Venkatraman and Shelten Gee Jao Yuen, and issued on April 7, 2015. RX-0368. Accordingly, Venkatraman is prior art to the '745 patent pursuant to 35 U.S.C. § 102(a)(1).

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obvious in view of Iwamiya in combination with Sarantos. *See* RIB at 197. For the reasons discussed above in the context of claim 9, Apple not shown, clearly and convincingly, that it would have been obvious to one of ordinary skill in the art to modify the device disclosed in Iwamiya with the teachings in Sarantos to implement a measurement of oxygen saturation with a reasonable expectation of success.

Accordingly, the evidence fails to clearly and convincingly show that claim 18 of the '745 patent is obvious in view of Iwamiya in combination with Sarantos and Venkatraman.

c. '745 Patent Claim 27

(i) Element [20 preamble]: "A system configured to measure one or more physiological parameters of a user, comprising:"

The preamble of claim 20 of the '745 patent requires "[a] system configured to measure one or more physiological parameters of a user," including "a physiological monitoring device." As discussed above in the context of the preamble of '745 patent claim 1, the evidence shows that Iwamiya discloses a "physiological monitoring device" because it contains a heart rate sensor. *See* RIB at 186, 197.

(ii) Element [20A]: "a plurality of light-emitting diodes configured to emit light in a first shape"

Claim 20 has a "plurality of light-emitting diodes" limitation that is identical to the limitation of claim 1. As discussed above in the context of claim 1, there is no dispute that Iwamiya discloses light-emitting diodes emitting light in a shape. *See* RIB at 186, 197.

(iii) Element [20B]: "a material configured to be positioned between the plurality of light-emitting diodes and tissue of the user when the physiological monitoring device is in use, the material configured to change the first shape into a second shape by which the light emitted from one or more of the

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plurality of light-emitting diodes is projected towards the tissue"

Claim 20 has a "material configured to change the first shape into a second shape" limitation that is identical to the limitation of claim 1. As discussed above in the context of claim 1, there is no dispute that Iwamiya discloses an "annular light guide unit" that is positioned between the light-emitting diodes and a user's wrist and changes the shape of the light from a first shape to a second shape. *See* RIB at 186-87, 197

(iv) Element [20C]: "a plurality of photodiodes configured to detect at least a portion of the light after the at least the portion of the light passes through the tissue, the plurality of photodiodes further configured to output at least one signal responsive to the detected light"

Claim 20 has a "plurality of photodiodes" limitation that is identical to the limitation of claim 1. As discussed above in the context of claim 1, there is no dispute that Iwamiya discloses a plurality of photodiodes that output a signal responsive to light that is reflected from a user's tissue. See RIB at 187-88, 197.

(v) Element [20D]: "a surface comprising a dark-colored coating, the surface configured to be positioned between the plurality of photodiodes and the tissue when the physiological monitoring device is in use, wherein an opening defined in the darkcolored coating is configured to allow at least a portion of light reflected from the tissue to pass through the surface"

Claim 20 has a "surface comprising a dark-colored coating" limitation that is identical to the limitation of claim 1. For the reasons discussed above in the context of claim 1, the undersigned finds that one of ordinary skill in the art would have had a reason to use a dark-colored coating in the device disclosed in Iwamiya and would have had a reasonable expectation of success.

(vi) Element [20E]: "a light block configured to prevent at least a portion of the light emitted from the plurality of light-emitting

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diodes from reaching the plurality of photodiodes without first reaching the tissue"

Claim 20 has a "light block" limitation that is identical to the limitation of claim 1. As discussed above in the context of claim 1, there is no dispute that Iwamiya discloses light blocks configured to prevent light from the light-emitting diodes from reaching the photodiodes without first reaching the tissue. *See* RIB at 189-90, 197.

(vii) Element [20F]: "a processor configured to receive and process the outputted at least one signal and determine a physiological parameter of the user responsive to the outputted at least one signal"

Claim 20 has a "processor" limitation that is identical to the limitation of claim 1. As discussed above in the context of claim 1, there is no dispute that Iwamiya discloses a CPU that receives and processes signals from the photodiodes to determine a physiological parameter. *See* RIB at 190-91, 197.

(viii) Element [20G]: "a processing device configured to wirelessly receive physiological parameter data from the physiological monitoring device, wherein the processing device comprises a user interface, a storage device, and a network interface configured to wirelessly communicate with the physiological monitoring device, and wherein the user interface includes a touch-screen display configured to present visual feedback responsive to the physiological parameter data"

Apple relies on Venkatraman in combination with Iwamiya for the limitation that the physiological parameter can be transmitted to a separate processing device. RIB at 197-98; Tr. (Sarrafzadeh) at 1108:1-23; RDX-7.129C. Apple identifies disclosures in Venkatraman describing a connection between a biometric monitoring device and a smartphone. *See* RX-0368 at 30:66-31:35, 57:20-59:13. Complainants argue that Apple has failed to show that Venkatraman discloses a "touch-screen display configured to present visual feedback responsive to the physiological parameter data." CRB at 132.

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In consideration of the parties' arguments, and for the reasons discussed above in the context of claim 15, the undersigned finds that one of skill in the art would have reason to connect the biometric device in Iwamiya with a smartphone as taught in Venkatraman with a reasonable expectation of success. See Tr. (Sarrafzadeh) at 1105:24-1106:11. The undersigned finds that one of ordinary skill in the art would have understood that a smartphone is a processing device comprising a user interface, a storage device, and a network interface. See id. at 1108:1-8. Moreover, Venkatraman explicitly discloses a smartphone app that displays biometric information on a touchscreen. See RX-0368 at 57:54-58:6 ("The user may be able to see these and other metrics on the dashboard . . . They may be able to access previous days by pressing a button or icon on a touchscreen."). Accordingly, each of the elements of the "processing device" limitation are clearly disclosed in Venkatraman, and one of ordinary skill would have reason to connect the biometric device in Iwamiya with a smartphone as taught in Venkatraman with a reasonable expectation of success.

> Element [27]: "at least one of the plurality of light-emitting (ix) diodes is configured to emit light of a first wavelength and at least one of the plurality of light-emitting diodes is configured to emit light of a second wavelength, the second wavelength being different than the first wavelength"

Claim 27 of the '745 patent depends from claim 20, further requiring that "at least one of the plurality of light-emitting diodes is configured to emit light of a first wavelength and at least one of the plurality of light-emitting diodes is configured to emit light of a second wavelength, the second wavelength being different than the first wavelength." There is no dispute that Iwamiya only discloses the use of one wavelength of light. See Tr. (Madisetti) at 1359:22-1366:1; RX-0130 at 10:34-38. Apple contends that this limitation would have been obvious to one of ordinary skill in the art in view of Iwamiya in combination with Sarantos, which provides

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that "it may be desirable to include separate light-emitting devices that are each able to emit different wavelengths of light" to measure other physiological parameters, such as blood oxygenation levels. RX-0366 at 13:44-58. Complainants argue that Apple has failed to show that one of ordinary skill in the art would have combined Iwamiya with Sarantos with a reasonable expectation of success. CIB at 228-30; CRB at 128-30.

For the same reasons discussed above in the context of '745 patent claim 9, the undersigned finds that Apple has not shown by clear and convincing evidence that one of ordinary skill would have been able to combine Iwamiya and Sarantos to use two wavelengths of light with a reasonable expectation of success. The only specific motivation for using multiple emitters disclosed in Sarantos is for measuring oxygen saturation, *see* RX-0366 at 13:44-47, and as discussed *supra*, the evidence does not clearly and convincingly show that one of ordinary skill in the art would have had a reasonable expectation of success in modifying Iwamiya to measure oxygen saturation.

Accordingly, the evidence fails to show that claim 27 of the '745 patent is obvious in view of Iwamiya in combination with Sarantos, because Apple has not shown, clearly and convincingly, that one of ordinary skill in the art would have had a reason to modify the device disclosed in Iwamiya with the teachings in Sarantos regarding the use of two wavelengths with a reasonable expectation of success.

3. Objective Considerations of Non-Obviousness

Complainants contend that certain objective indicia discussed above in the context of the Poeze patents support a finding of non-obviousness for the claims of '745 patent, including Apple's skepticism and failures in implementing wrist-based pulse oximetry and the commercial

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success of the Apple Watch Series 6. CIB at 233-34; CRB at 132-33. Apple disputes whether this evidence is relevant to the obviousness of the '745 patent claims. RIB at 199-201; RRB at 109-110.

For the reasons discussed above in the context of the Poeze patents, this evidence does not weigh significantly against a finding of obviousness.⁸⁷ For the reasons discussed above, however, the evidence does not provide a clear and convincing showing of obviousness for the claims of '745 patent.

H. Invalidity - Written Description and Enablement

Apple contends that the asserted claims of the '745 patent are invalid for lack of written description and/or indefiniteness pursuant to 35 U.S.C. § 112. RIB at 201-04; RRB at 110-11.

1. Written Description (Claims 1, 9, 20, 27)

Apple argues that claims 1 and 20 of the '745 patent, from which asserted claims 9 and 27 depend, are invalid for lack of written description with respect to a "surface comprising a dark-colored coating . . . wherein an opening defined in the dark-colored coating is configured to allow at least a portion of light reflected from the tissue to pass through the surface" in an embodiment where the sensors are in a reflectance configuration. RIB at 201-02. In the context of the fingertip sensor 300 depicted in Figures 3 and 4, the specification describes a "light-absorbing detector filter 306 "having a top surface coated with a "light-absorbing material" that "can be a black opaque material or coating or any other dark color or coating configured to absorb light." JX-009 at 9:31-36, Fig. 3, Fig. 4A. The specification describes a separate embodiment depicted in Figures 7A and 7B that is "a 3D reflective pulse oximetry sensor 700"

⁸⁷ The evidence of commercial success is not relevant because the Accused Products have not been shown to practice claims of the '745 patent.

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with an annular "light block 706." *Id.* at 10:40-51, Fig. 7A, Fig. 7B. Dr. Sarrafzadeh testified that "there is no description on how to combine these embodiments in the description of the patent." Tr. (Sarrafzadeh) at 1110:24-1111:2. Apple argues that the specification thus fails to describe the claimed invention "as an integrated whole" with a dark-colored coating used with a reflectance sensor. RIB at 202; RRB at 110 (citing *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1349 (Fed. Cir. 2013).

Complainants submit that the specification explicitly links the two embodiments together: "In other embodiments, for example, as describe [sic] below with respect to FIGS. 7A and 7B, the 3D sensor 300 can be arranged to detect light that is reflected by the tissue measurement site 102." JX-009 at 7:4-14. Dr. Madisetti identified a light concentrator (labeled 308 and 708 in the specification) that is common to both the Figure 3 and Figure 7 embodiments and "links all these embodiments together." Tr. (Madisetti) at 1365:7-1366:8 (citing JX-009 at 9:30-40).

Complainants argue that these disclosures show that the two embodiments are not distinct but are linked together. CIB at 235-36; CRB at 133-34.

The evidence fails to show, clearly and convincingly, a lack of adequate written description support for the "dark-colored coating" limitations of claims 1 and 20. The undersigned agrees with Complainants that the specification describes common elements in the Figure 3 fingertip sensor and the Figure 7 reflectance sensor, explicitly suggesting that "the 3D sensor 300 can be arranged to detect light that is reflected by the tissue measurement site," thus supporting Dr. Madisetti's opinion that one of ordinary skill would link these embodiments. JX-009 at 7:4-14; Tr. (Madisetti) at 13:65:7-1366:8. Moreover, with respect to the light blocker 706 in the Figure 7 embodiment, the specification explicitly provides that "[t]he light blocker 706 and the cover 707 can be made of any material that optically isolates the light concentrator 708

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and the detector 710." *Id.* at 11:14-16, Fig. 7B. ⁸⁸ This disclosure of "any material" for light blocking further supports Dr. Madisetti's opinion that the "light-absorbing material" described earlier in the specification in reference to Figure 4A, including "a black opaque material or coating or any other dark color or coating configured to absorb light," is linked to the Figure 7 embodiment. JX-009 at 9:31-36; Tr. (Madisetti) at 1365:7-1366:8; CDX-0012C.081. The Federal Circuit has held that "the description requirement does not demand any particular form of disclosure, or that the specification recite the claimed invention *in haec verba*." *Ariad*, 598 F.3d at 1352 (citations removed). Apple's argument that the dark-colored coating is distinct from the reflectance sensor embodiment is unconvincing in view of these disclosures in the specification.

Accordingly, based on the evidence of record, Apple has not shown clearly and convincingly that claims 1 or 20 of the '745 patent are invalid for lack of written description.

2. Indefiniteness (Claims 15, 18)

Apple argues that claim 15 of the '745 patent, from which asserted claim 18 depends, is invalid for indefiniteness with respect to the limitation requiring a plurality of photodiodes "arranged in an array having a spatial configuration corresponding to a shape of the portion of the tissue measurement site encircled by the light block." RIB at 202-04; RRB at 110-11.

Dr. Sarrafzadeh testified that one of ordinary skill in the art would not have been able to determine which shape corresponds to an arrangement of photodiodes, providing an example of four photodiodes that could correspond to many different shapes. Tr. (Sarrafzadeh) at 1111:3-18; RDX-7.134C. Apple argues that this ambiguity regarding how a spatial configuration

⁸⁸ Figure 7 also appears to show shows a positioning of a surface of the light blocker 706 between the tissue and photodiode, similar to the positioning of element 306 in Fig. 3.

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corresponds to a shape renders this limitation indefinite, because one of skill in the art would not be able to determine the scope of the invention with reasonable certainty. RIB at 202-04 (citing Nautilus, Inc. v. Biosig Instruments, Inc., 57 U.S. 898, 910 (2014)).

Complainants argue that Apple has not met its clear and convincing burden to prove indefiniteness. CIB at 236-38. Complainants submit that Dr. Sarrafzadeh failed to consider the surrounding claim language and other evidence in the intrinsic record defining the scope of this limitation. Id. at 237-38. Complainants submit that the "shape" of the configuration of photodiodes is defined by the light block, which has "a circular shape." See JX-009 at 16:43-52. Complainants further rely on statements in the prosecution history of the '745 patent that discuss "sufficient detectors to represent such shapes," with an example that "six or more detectors could be arranged in an annular shape and meet the recited limitation." CX-1760 at 322; see also id. (indicating that two or three detectors would be insufficient). Dr. Madisetti relied on these disclosures and offered his opinion that this limitation "would be understood by a person having ordinary skill in the art as requiring a sufficient number of detectors, such that when arranged together in an array can match -- have a close similarity or present the at least partially circular shape of the irradiated portion of the tissue measurement site." Tr. (Madisetti) at 1366:13-1367:19.

In consideration of the parties' arguments, the undersigned agrees with Complainants that Apple has not shown, clearly and convincingly, that the claimed arranged of photodiodes in a "spatial configuration corresponding to a shape" is indefinite. In particular, Dr. Sarrafzadeh's testimony relying on hypothetical shapes drawn through an arrangement of photodiodes fails to read this term within the context of claim 15's surrounding language. See CIB at 236-37. The "shape" referenced in this limitation is "a shape of the portion of the tissue measurement site

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encircled by the light block." To determine whether a device meets this limitation, one of ordinary skill in the art would not draw arbitrary shapes around the photodiodes, as Dr. Sarrafzadeh appears to suggest, but would rather assess this limitation in relation to the "tissue measurement site encircled by the light block." *See* Tr. (Madisetti) at 1366:13-1367:10. Apple has failed to show that one of ordinary skill in the art would be unable to determine whether the limitation is met by comparing the arrangement of photodiodes to the shape of the encircled tissue. 89

Accordingly, Apple has not shown by clear and convincing evidence that claim 15 of the '745 patent is invalid for indefiniteness.

I. Prosecution Laches

Apple contends that the asserted claims of the '745 patent are unenforceable due to prosecution laches. RIB at 204-05. Apple identifies the filing dates for provisional applications and continuation applications in the family of the '745 patent and ties them to the release dates for Apple Watch products. *Id.* Apple argues that the '745 patent should be held unenforceable due to prosecution laches because the application for the '745 patent was filed nearly five years after the first provisional patent application in the family, and during this timeframe Apple invested heavily in the development of Apple Watch products and growing the market for wearable technology. *Id.*; RRB at 112.

Complainants argue that Apple has failed to show any unreasonable or unexplained delay in the prosecution of the '745 patent. CIB at 238-39. Mr. Stoll described a "continuous

⁸⁹ As discussed above in the context of the domestic industry requirement, this limitation is met by photodiodes arranged in a circular array around the light block in the '745 DI Products. As discussed above in the context of obviousness, this limitation is, at least, *prima facie* obvious in view of Iwamiya's description of "plural light receiving units" that are "disposed on the same circumference" as the light block.

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unbroken chain of patent prosecution." Tr. (Stoll) at 1415:2-10; *see* CX-1760 ('745 patent prosecution history). Complainants submit that the filing dates for applications in the '745 patent family in 2015, 2016, 2018, 2019, and 2020 demonstrate active prosecution of patents in this family. CRB at 134.

In consideration of the parties' arguments, the undersigned finds that Apple has failed to show that the '745 patent should be found unenforceable due to prosecution laches. As discussed above in the context of the Poeze patents, prosecution laches requires a showing of unreasonable and inexcusable delay, and evidence sufficient to make that showing is lacking here. The record shows continuous prosecution activity from the filing of the original provisional application in 2015 to the issuance of the '745 patent in 2020. *See* JX-009; CX-1760. Apple's arguments tying certain patent application filings to release dates for the Apple Watch is unpersuasive, and the timeline is not consistent with Apple's allegations that Masimo drafted claims to cover the Apple Watch. *See* CIB at 204-05. Apple has not identified delay in the prosecution of the '745 patent that would warrant a finding of prosecution laches.

VI. U.S. PATENT NO. 7,761,127

The '127 patent is entitled "Multiple Wavelength Sensor Substrate," naming inventors Ammar Al-Ali, Mohamed Diab, Marcelo Lamego, James P. Coffin, and Yassir Abdul-Hafiz and claiming priority to a provisional application filed on March 1, 2005, and a non-provisional application filed on March 1, 2006. JX-007.

⁹⁰ As discussed above, the Apple Watch Series 0 is prior art to the '745 patent, so any claims drafted to cover this product would have been invalid as anticipated. In addition, the '745 patent issued before the release of the Apple Watch Series 6 and the other Accused Products in this investigation, so the claims of the '745 patent could not have been drafted based on any released Apple Watch with a blood oxygen feature.

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A. Specification

The specification of the '127 patent describes a physiological sensor with emitters transmitting radiation at multiple wavelengths and a thermal mass that stabilizes a bulk temperature for the emitters. JX-007 at Abstract, 10:22-26, Fig. 12. "A temperature sensor 1230 is thermally coupled to the thermal mass 1220" to measure the bulk temperature. *Id.* at 10:26-31. The specification explains that the wavelengths of the light emitters "are determinable as a function of the drive currents 1210 and the bulk temperature 1202." *Id.*

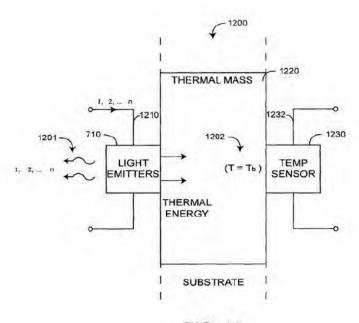


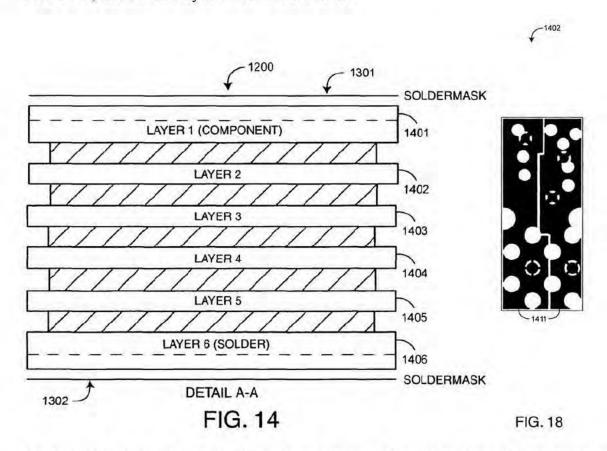
FIG. 12

Id. at Fig. 12. In particular, the operating wavelength λ_a of each light emitter is determined according to a function of the bulk temperature T_b , the drive current for the light emitter I_{drive} , and the total drive current for all light emitters ΣI_{drive} . Id. at 10:32-39.

The specification describes one embodiment where LEDs are mounted on a substrate, which is "configured with a relatively significant thermal mass, which stabilizes and normalizes the bulk temperature so that the thermistor measurement of bulk temperature is meaningful." *Id.*

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at 10:67-11:4. A substrate depicted in Figure 14 has "a component layer 1401, inner layers 1402-1405, and a solder layer 1406." *Id.* at 11:5-10.



Id. at Fig. 14, Fig. 18. Figure 18 depicts inner layer 1402 having "substantial metallized areas 1411 that provide a thermal mass 1220 (FIG. 12) to stabilize a bulk temperature for the emitter array 700 (FIG. 12)." Id. at 11:10-13.

B. Claims

Complainants assert claim 9 of the '127 patent, which depends from claim 7. The limitations of these claims are recited below:

- 7. A physiological sensor capable of emitting light into tissue and producing an output signal usable to determine one or more physiological parameters of a patient, the physiological sensor comprising:
- a thermal mass;

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- a plurality of light emitting sources, including a substrate of the plurality of light emitting sources, thermally coupled to the thermal mass, the sources having a corresponding plurality of operating wavelengths, the thermal mass disposed within the substrate;
- a temperature sensor thermally coupled to the thermal mass and capable of determining a bulk temperature for the thermal mass, the operating wavelengths dependent on the bulk temperature; and
- a detector capable of detecting light emitted by the light emitting sources after tissue attenuation, wherein the detector is capable of outputting a signal usable to determine one or more physiological parameters of a patient based upon the operating wavelengths.

JX-007 at 19:35-53.

9. The physiological sensor of claim 7 wherein the temperature sensor comprises a thermistor.

Id. at 19:58-59.

C. Level of Ordinary Skill in the Art

There is no dispute regarding the appropriate level of ordinary skill in the art for the '127 patent in this investigation. *See* CIB at 239; RIB at 209. Dr. Sarrafzadeh testified that a person of ordinary skill in the art would be a person with "working knowledge of physiological monitoring and thermal management technology, ... a Bachelor of Science in an academic discipline emphasizing design of electrical and thermal technologies in combination with training or at least one or two years of related work experience with processing of data information, including but not limited to physiological monitoring technology" and "if somebody had a Master of Science in relevant academic discipline with less than a year of related work experience, that would qualify." Tr. (Sarrafzadeh) 1047:17-1048:4. Mr. Goldberg used this same level of ordinary skill for his analysis. *See* Tr. (Goldberg) at 1391:22-24.

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D. Claim Construction

The parties have agreed that a "plurality of wavelengths" is "two or more operating wavelengths." *See* CIB at 239; RIB at 209; Updated Joint Proposed Claim Construction Chart at 1, EDIS Doc. ID 763856 (Feb. 23, 2022).

In their post-hearing briefs, the parties dispute the construction of two terms in claim 7 of the '127 patent: "thermal mass" and "bulk temperature for the thermal mass." CIB at 239-47; RIB at 213-15; CRB at 135-41; RRB at 114-23.91

1. "thermal mass"

"[A] thermal mass" is the first limitation in the body of claim 7, and the term "thermal mass" also appears in the "plurality of light emitting sources" limitation, requiring a substrate of the light emitting sources to be "thermally coupled to the thermal mass," and in the "temperature sensor" limitation of claim 7, which requires "a temperature sensor thermally coupled to the thermal mass and capable of determining a bulk temperature for the thermal mass, the operating wavelengths dependent on the bulk temperature." JX-007 at 19:39-48.

Apple contends that a "thermal mass" is a component that stabilizes a bulk temperature.

RIB at 213-14; RRB at 116-19. Apple states that the claimed thermal mass "stabilizes a bulk

⁹¹ Complainants argue that Apple never identified the terms "thermal mass" and "bulk temperature" during claim construction but relied on certain constructions to argue non-infringement. CIB at 239. Apple argues that Complainants' proposed claim constructions are untimely and that, "[p]rior to Complainants' initial post-hearing brief, no party requested constructions of 'thermal mass' or 'bulk temperature for the thermal mass." RRB at 114. Given that, *inter alia*, both parties addressed claim construction in their initial post-hearing briefs, and testimony regarding this issue was presented at the hearing without objection, the parties' claim construction arguments will be considered. *See, e.g.*, Tr. (Goldberg) at 618:9-21, 624:10-25; Tr. (Sarrafzadeh) at 1069:2-14, 1081:20-1082:8.

⁹² These limitations mirror disclosures in the specification, wherein "[a] temperature sensor 130 is thermally coupled to the thermal mass 1220, wherein the temperature sensor 1232 provides a temperature sensor output 1232 responsive to the bulk temperature 1202 so that the wavelengths are determinable as a function of the drive currents 1210 and the bulk temperature 1202." JX-007 at 10:26-31.

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temperature," such that "the thermistor is then able to meaningfully measure that 'bulk temperature." RIB at 213. Apple argues that the term "thermal mass" does not refer simply to "the physical property of 'thermal mass' that is possessed by all objects with mass." *Id.* Apple further contends that the existence of a thermal mass cannot simply be assumed "if the sensor estimates wavelength using a temperature measurement." RRB at 117. In the context of invalidity, Apple argues that Complainants' interpretation of the "thermal mass" limitation would cover any circuit board with multiple layers. RIB at 234-35. Apple submits that the consistent disclosures in the specification of the '127 patent requires that the "thermal mass" is a component that stabilizes a bulk temperature. *Id.* at 213-14; RRB at 116-19.

Complainants propose to construe "thermal mass" to mean a "mass that provides a bulk temperature that can be used to reliably estimate the operating wavelengths of the LEDs." CIB at 240-44; CRB at 136-38. Complainants argue that the term "thermal mass" is "described in terms of the ability to estimate wavelength from the temperature measurement of the thermal mass." CIB at 243. Complainants do not specifically dispute that the "thermal mass" stabilizes a bulk temperature but argue that the temperature is not required to be constant—only sufficient to be used to reliably estimate the operating wavelengths of the LEDs. *Id.* at 234-44; CRB at 136-37. Complainants also argue that there is no basis for any requirement that the "thermal mass" have a minimum thickness. CIB at 234; CRB at 136.

Upon review of the parties' submissions, the undersigned finds that the term "thermal mass" refers to a mass that stabilizes a bulk temperature. This is consistent with the use of the term within the specification, which provides that "[a] thermal mass 1220 is disposed proximate

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to the emitters 710 so as to stabilize a bulk temperature 1202 for the emitters." *Id.* at 10:24-26.⁹³ The specification further describes a substrate that is "configured with a relatively significant thermal mass, which stabilizes and normalizes the bulk temperature so that the thermistor measurement of bulk temperature is meaningful." *Id.* at 10:67-11:4. In a specific embodiment, a layer of a substrate is described as having "substantial metallized areas 1411 that provide a thermal mass 1220 (FIG. 12) to stabilize a bulk temperature for the emitter array 700 (FIG. 12)." *Id.* at 11:10-13.

The specification thus clearly describes a "thermal mass" that stabilizes a bulk temperature, and the parties do not appear to dispute this fact, although only Apple's construction explicitly incorporates temperature stabilization. *See* RRB at 116-17; CIB at 240 (citing the specification's disclosures that the "thermal mass" as "disposed proximate the emitters so as to stabilize a bulk temperature for the emitters" and "relatively significant so as to stabilize and normalize the bulk temperature."). ⁹⁴ Both Dr. Sarrafzadeh and Mr. Goldberg agreed that the '127 patent describes the claimed thermal mass as stabilizing a bulk temperature. *See* Tr. (Sarrafzadeh) at 1069:7-22; Tr. (Goldberg) at 643:4-12. ⁹⁵

⁹³ Claims 1 and 26 include "thermal mass" limitations that mirror these specification disclosures, describing "a thermal mass disposed proximate to the emitters and within the substrate so as to stabilize a bulk temperature for the emitters." JX-007 at 19:9-11 (claim 1), 21:5-7 (claim 26).

⁹⁴ In the context of invalidity, Complainants argue that prior art references lack a "thermal mass" that "would stabilize a bulk temperature of the substrate," or a component "that functions as a thermal mass by stabilizing a bulk temperature." CIB at 279, 281.

⁹⁵ The parties also agree that the term "thermal mass," as used in the patent, does not correspond simply to a physical property possessed by any mass. *See* Tr. (Goldberg) at 639:24-640:3 (noting distinction between "thermal mass in the context of the patent or the thermal mass . . . as a scientific principle of physics"); Tr. (Sarrafzadeh) at 1071:17-21 (distinguishing between "thermal mass of the patent" and the physical property of thermal mass of "any material"); RRB at 124-25.

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While Complainants do not explicitly dispute that the claimed thermal mass stabilizes a bulk temperature, they argue that Apple's interpretation of stabilization is too narrow, requiring a minimum thickness for the thermal mass or stabilization at a constant temperature. CIB at 243; CRB at 136. Apple's proposed construction does not require a minimum thickness or a constant temperature, however. *See* RRB at 118-19. Dr. Sarrafzadeh merely offered his opinion that certain metal layers could not be a "thermal mass" where "[t]hey are not really thick enough to provide any . . . thermal stability." Tr. (Sarrafzadeh) at 1066:4-9.96 The undersigned thus agrees with Apple that the claimed "thermal mass" is a mass that stabilizes a bulk temperature. 97

Complainants fail to explain why their proposed construction omits any requirement for temperature stabilization, arguing only that the "thermal mass" is a "mass that provides a bulk temperature that can be used to reliably estimate the operating wavelengths of the LEDs." CIB at 240; see CRB at 136-38. Complainants further define "bulk temperature" to be "a single temperature used to estimate the operating wavelengths of all the LEDs." CIB at 244. Substituting this definition into Complainants' construction of "thermal mass," Complainants' proposed definition of "thermal mass" becomes "a mass that provides a single temperature used to estimate the operating wavelengths of all the LEDs, that can be used to reliably estimate the

⁹⁶ He also observed temperature variations in a circuit board, finding that it was "not at a uniform temperature through time or spatially" and that the temperature "is not stabilized." *Id.* at 1078:23-1079:9. Dr. Sarrafzadeh's analysis is consistent with Apple's proposed construction and the specification's description of "a relatively significant thermal mass, which stabilizes and normalizes the bulk temperature." JX-007 at 10:67-11:4, 11:10-13.

⁹⁷ Apple's proposed construction describes the "thermal mass" as a "component" that stabilizes a bulk temperature, RIB at 213-14, but Apple does not explain why the claim term "mass" has been replaced with the word "component," which does not appear in the claims or the relevant portions of the specification. Complainants have used the word "mass" in their proposed construction, see CIB at 240, and there does not appear to be any meaningful dispute regarding the meaning of the word "mass." Accordingly, the undersigned shall construe the term "thermal mass" without substituting another word for "mass."

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operating wavelengths of the LEDs"—or, effectively, "a mass that provides a single temperature used to reliably estimate the operating wavelengths of all the LEDs." Complainants also make clear that the "single temperature" required for a bulk temperature need not be a uniform temperature but is simply a "single measurement." *See* CIB at 246 ("bulk temperature" need not be a "uniform or average temperature."); *id.* at 247 (explaining that bulk temperature "is a single measurement for the thermal mass").

The intrinsic evidence fails to indicate that any mass of a non-uniform temperature, from which a single temperature measurement can be provided to estimate the operating wavelengths of all LEDs is, *ipso facto*, a "thermal mass."

First, Complainants' construction merely restates the language in the "temperature sensor" limitation of claim 7 while providing no meaning to the limitation requiring a "thermal mass." *See* JX-007 at 19:45-48 (claim 7 requiring "a temperature sensor thermally coupled to the thermal mass and capable of determining a bulk temperature for the thermal mass, the operating wavelengths dependent on the bulk temperature"). The Federal Circuit has held that "[i]t is highly disfavored to construe terms in a way that renders them void, meaningless, or superfluous." *Wasica Finance GmbH v. Continental Automotive Systems, Inc.*, 853 F.3d 1272, 1288 n.10 (Fed. Cir. 2017).

Further, the prosecution history of the '127 patent weighs against Complainants' approach. Complainants rely on the prosecution history to show that the claims of the '127 patent were distinguished from prior art without a "thermal mass," CIB at 242, CRB at 137-38, but it is clear from this record that the examiner did not understand the term "thermal mass" to only require an estimate of the operating wavelengths of the LEDs based on a single temperature measurement. In the relevant portion of the prosecution history of the '127 patent, the examiner

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considered a prior art reference, U.S. Patent No. 5,259,381 to Cheung et al. (RX-0406, "Cheung"), finding that Cheung "discloses all the elements of the current invention . . . except for the sensor comprising a thermal mass disposed proximate the emitters, wherein the thermal mass stabilizes a bulk temperature of the emitters." JX-008 at 363, 433 (MASITC 00077988, 00078058) (rejecting, inter alia, prosecution claim 5, which ultimately issued in amended form as claim 7). 98 When discussing the prosecution history at the hearing, Mr. Goldberg agreed that "Cheung does not have a thermal mass." Tr. (Goldberg) at 1395:13-15. Despite the lack of a "thermal mass," the examiner recognized that Cheung discloses a "temperature sensor" and a method for "determining a plurality of operating wavelengths of the light emitting sources so that one or more physiological parameters can be determined based upon the operating wavelengths." JX-008 at 362 (MASITC 00077987); see RX-0406 at Abstract ("[A] temperature sensor (50) is included in the sensor (12) to produce a signal indicative of sensor temperature. This signal is interpreted by the oximeter circuitry including, for example, a microcomputer (16), where the effect of temperature on wavelength is compensated for."). In response to this rejection and following an interview with the examiner, Complainants' counsel amended all of the independent claims of the '127 patent. JX-008 at 399-407. 99

Cheung's temperature sensor measures a single temperature that is used to "accurately determine" the wavelengths of two LEDs for oxygen saturation measurements. *See* RX-0406 at

⁹⁸ Prosecution claim 5 at that time required, *inter alia*, "a temperature sensor thermally coupled to the thermal mass and capable of determining a bulk temperature for the thermal mass, the operating wavelengths dependent on the bulk temperature" and the determination of "one or more physiological parameters of a patient based upon the operating wavelengths." JX-008, at 38 (MASITC 00077663).

⁹⁹ In response to rejections based on obviousness in view of Cheung in combination with additional prior art references, including U.S. Patent No. 6,360,113 ("Dettling '113") and U.S. Patent Pub. No. 2002/0154665 ("Funabashi et al. '665), the claims were amended to specify that the thermal mass is disposed within a substrate. *See* JX-008 at 363-64, 399-407.

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13:20-32 ("[A] temperature sensor 50 . . . is employed to produce a signal that indicates the temperature of sensor assembly 48. . . . [T]his signal, when combined with information about the coding resistor 52 value, allows microcomputer 16 to accurately determine the wavelengths of the light emitted by LEDs 40 and 42 and subsequently produce an accurate determination of oxygen saturation."); RRB at 115 (quoting Cheung). Complainants' proposed construction would thus fail to distinguish claim 7's requirement for a "thermal mass" over a reference that the examiner (and Complainants' expert) recognized does not have a thermal mass.

Accordingly, Complainants' proposed construction is unsupported—a "thermal mass" is not merely any mass from which a single temperature measurement can be used to estimate the operating wavelengths of the LEDs. ¹⁰⁰

* * *

Accordingly, "thermal mass" shall be construed to mean a mass that stabilizes a bulk temperature.

2. "bulk temperature for the thermal mass"

The "temperature sensor" limitation of claim 7 describes "a bulk temperature for the thermal mass, the operating wavelengths dependent on the bulk temperature." JX-007 at 19:45-

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To the extent Complainants seek to argue that their proposed construction requires, in addition, "reliably" estimating wavelength in a manner that improves over Cheung (see CIB at 285), such an addition is not supported by the evidence. As discussed above, the examiner viewed Cheung as meeting the claim requirements except for that of a "thermal mass" stabilizing a bulk temperature. Complainants' proposed claim construction, moreover, does not include any proviso requiring a greater degree of accuracy than Cheung. Complainants' infringement analysis also does not provide any comparison of the Accused Products to the accuracy provided in Cheung. Moreover, even if greater accuracy were shown in the Accused Products, the evidence shows that there are multiple ways to achieve greater accuracy in wavelength estimation apart from inclusion of a thermal mass, and some of these methods can be used in combination with a temperature measurement. See RRB at 115-16; RX-0035.0086. The existence of a thermal mass does not simply follow, as a matter of logic, from reliable wavelength estimation using, inter alia, a single temperature measurement. See RIB at 114-115.

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48. As discussed above in the context of "thermal mass," the specification provides that "[a] thermal mass 1220 is disposed proximate to the emitters 710 so as to stabilize a bulk temperature 1202 for the emitters." Id. at 10:24-26. The specification further provides that "[a] temperature sensor 130 is thermally coupled to the thermal mass 1220, wherein the temperature sensor 1230 provides a temperature sensor output 1232 responsive to the bulk temperature 1202 so that the wavelengths are determinable as a function of the drive currents 1210 and the bulk temperature 1202." *Id.* at 10:26-31. The specification describes two distinct methods for determining the wavelengths of the emitters, distinguishing between a method using the bulk temperature (T_b) and a method using the temperatures of individual light emitters (T_a) . Id. at 10:32-48. In a "bulk temperature" embodiment, a thermistor is used "to determine the bulk temperature of LEDs 801 (FIG. 8) mounted on the substrate 1200," and "[t]he substrate 1200 is configured with a relatively significant thermal mass, which stabilizes and normalizes the bulk temperature so that the thermistor measurement of bulk temperature is meaningful." *Id.* at 10:67-11:4.

Apple does not propose an explicit construction for "bulk temperature" but argues that the "bulk temperature for the thermal mass" should follow the 'ordinary usage of the adjective 'bulk,' which is the majority or greater part." RIB at 215. Apple, in support, cites certain deposition testimony of one of the named inventors indicating that it is an "average" or "representative" temperature. Id. (citing RX-1195C (Abdul-Hafiz Dep. Tr.) at 99:1-19 ("[T]he bulk temperature means . . . I call it the representative temperature . . . a representative temperature of the whole bulk, and that's what we call bulk temperature.")) Apple also relies on a statement made by Complainants' counsel at the Markman hearing that "people understand bulk is the vast majority." Markman H'rng Tr. at 42:6-9. Apple further distinguishes a "bulk temperature" from "a local temperature" for one part of the mass. RIB at 215 ("the temperature

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sensor measures a 'bulk temperature' that is different from a regular temperature measurement by a temperature sensor, which is a local temperature measurement"); *see also* RIB at 214-15; RRB at 116-19.

Complainants argue that a "bulk temperature" is "a single temperature used to estimate the operating wavelength of all the LEDs." CIB at 244. Complainants argue that the claimed bulk temperature does not need to be an average temperature or a uniform temperature for the thermal mass, relying on the claim language describing the "bulk temperature" as a single temperature used to estimate the operating wavelengths of all the LEDs. CIB at 244-47; CRB at 138-41. Complainants argue that the "bulk temperature" is not necessarily an "average" temperature, but rather is a "single, 'representative' measurement." CIB at 244-45. Complainants rely on the testimony of Yassir Abdul-Hafiz, one of the named inventors, who described a "bulk temperature" as the "representative temperature," which is different from a "local temperature" at a "spot that we are measuring." RX-1195C (Abdul-Hafiz Dep. Tr.) at 99:1-15. He further explained that the temperature of a "thermal mass" can be "a representative temperature of the whole bulk, and that's what we call bulk temperature." *Id.* at 99:16-19. His co-inventor Mr. Diab described the "bulk temperature" as a "baseline that is defined by this substrate, and what we found in this invention is that if you measure that baseline and -- with a certain quality for the substrate, . . . you can have a very good correlation to the inside temperature of each LED." RX-1200C (Diab Dep. Tr.) at 137:12-138:8.

In consideration of the parties' arguments, the undersigned construes "bulk temperature of the thermal mass" to mean a representative temperature for the thermal mass. The parties do not appear to dispute that the "bulk temperature" claimed in the '127 patent is a representative temperature for the thermal mass, in accordance with Mr. Abdul-Hafiz's testimony. This

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construction is also consistent with the "bulk temperature" embodiment in the specification, where a thermistor is used "to determine the bulk temperature of LEDs 801 (FIG. 8) mounted on the substrate 1200," and "[t]he substrate 1200 is configured with a relatively significant thermal mass, which stabilizes and normalizes the bulk temperature so that the thermistor measurement of bulk temperature is meaningful." *Id.* at 10:67-11:4. Omplainants' proposed construction improperly reads out the "thermal mass" from the limitation "bulk temperature for the thermal mass." This is improper, for the same reasons discussed above in the context of the construction for "thermal mass," because it would fail to give meaning to these terms and would be inconsistent with the prosecution history. Complainants' proposed construction requiring only that the bulk temperature be used to estimate the operating wavelength of all the LEDs would be met by Cheung, which does not include a "thermal mass." *See* RX-0406 at 13:20-32. 102

* * *

Accordingly, "bulk temperature for the thermal mass" shall be construed to mean a representative temperature for the thermal mass.

E. Infringement

Complainants allege that the Accused Products infringe claim 9 of the '127 patent, relying on the testimony of Mr. Goldberg. CIB at 248-66; CRB at 141-54; Tr. (Goldberg) at 612:9-626:16. Apple disputes whether the Accused Products meet the limitations requiring a

¹⁰¹ Complainants argue that Apple's proposed interpretation of this limitation would read out the preferred embodiment in the specification using a single thermistor, CIB at 246-47, but Apple agrees that "a 'bulk temperature' could be measured by a properly positioned single thermistor if the thermal mass were stabilized at the bulk temperature." RRB at 122.

¹⁰² Complainants' proposed construction would also be superfluous, because the subsequent language in the claim already requires "the operating wavelengths dependent on the bulk temperature." *See* JX-007 at 19:45-49.

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"thermal mass" and a temperature sensor "capable of determining a bulk temperature for the thermal mass," relying on the testimony of Dr. Sarrafzadeh. RIB at 209-24; RRB at 114-30; Tr. (Sarrafzadeh) at 1064:8-1084:5. For the reasons discussed below, the undersigned finds that the Accused Products have not been shown to infringe claim 9 of the '127 patent by a preponderance of the evidence.

1. Element [7 preamble]: "physiological sensor"

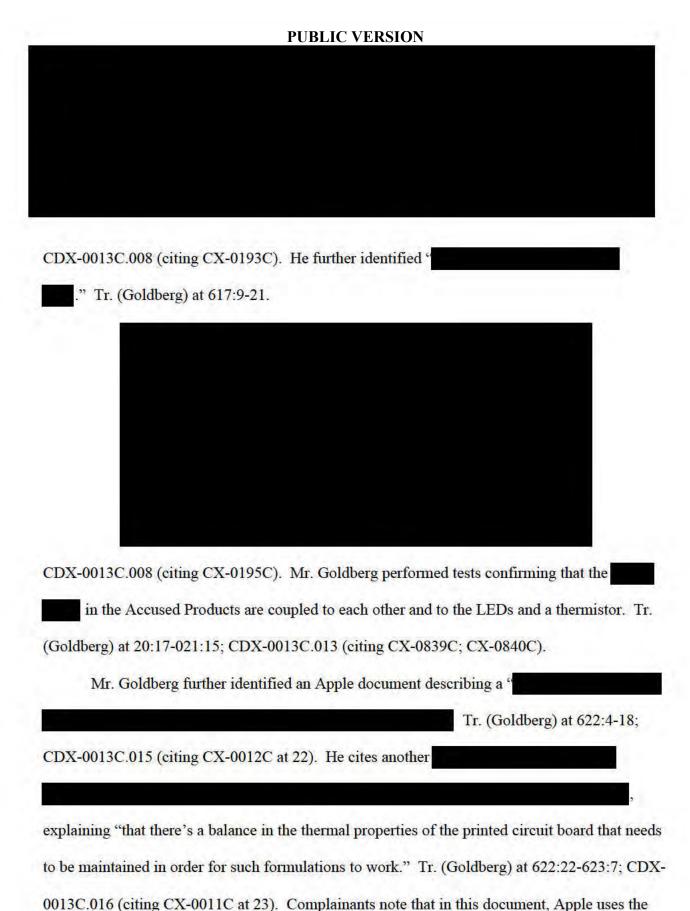
There is no dispute that the Accused Products meet the limitations of the preamble of claim 7, describing "[a] physiological sensor capable of emitting light into tissue and producing an output signal usable to determine one or more physiological parameters of a patient." Complainants identify evidence that the Accused Products have LEDs capable of emitting light to a user's wrist that is reflected back to photodiodes and used to determine blood oxygen levels. CIB at 254; Tr. (Goldberg) at 616:4-16; CDX-0013C.007; CX-1724 at 3. Accordingly, the evidence shows that the Accused Products have physiological sensors that meet the preamble limitations of claim 7.

2. Element [7A]: "a thermal mass"

Mr. Goldberg identified "	" of a printed circuit board
("PCB") in the Accused Products, which Comp	lainants identify as the claimed "thermal mass."
CIB at 254-58; Tr. (Goldberg) at 617:9-618:21.	Mr. Goldberg identified "
	." Tr. (Goldberg) at 617:9-21.

¹⁰³ The parties have stipulated that the preambles of the asserted patents are limiting. *See* Joint Stipulation of Facts ¶ 9, EDIS Doc. ID 770692 (May 13, 2022).

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term "thermal mass." CX-0011C at 23. Mr. Goldberg recognized that the Accused Products use a single thermistor to measure the temperature of the PCB, and "the thermal mass is configured in a manner that the thermal coupling between the LEDs and the thermistor are such that the bulk temperature as measured by the thermistor is meaningful, and that meaningfulness has to do with being able to use that bulk temperature to determine the operating wavelengths." Tr. (Goldberg) at 624:7-25. Complainants argue that

that allows for the measurement of a single temperature that can be used to reliably estimate the wavelengths of the plurality of LEDs. CRB at 141-43, 147-48.

Apple argues that Mr. Goldberg failed to show that the Accused Products have the accused "thermal mass." RIB at 218-19. Apple cites testimony from named inventor Mohamed Diab, who agreed that "some form of experiment" would be necessary to determine whether an object stabilizes temperatures in accordance with the invention. See Tr. (Diab) at 238:15-19. Apple argues that Mr. Goldberg only performed tests regarding thermal conductivity, which are not sufficient to show temperature stabilization. See Tr. (Sarrafzadeh) at 1070:22-1071:5, 1080:11-1081:18; RDX-7.70. Apple submits that Complainants have failed to articulate what thermal properties would be sufficient to establish that a "thermal mass" stabilizes a bulk temperature. RRB at 123-24. With respect to the use of the term "thermal mass" in an Apple presentation, Dr. Mannheimer explained that the term referred to a physical property related to an object's heat capacity, and not to the "thermal mass" referenced in the '127 patent. CX-0289C (Mannheimer Dep. Tr.) at 148:8-156:1; see also CX-0291C (Mehra Dep. Tr.) at 180:8-182:17 ("I don't know what that refers to"); Tr. (Sarrafzadeh) at 1071:13-1072:7 ("the thermal mass here is not the thermal mass of the patent").

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Tr. (Sarrafzadeh) at 1074:8-1078:22; RDX-7.65C; RDX-7.66C.
CX-0322b-C.0010.
Apple also argues that the in the PCB of the Accused Products do not
comprise a "thermal mass" because to stabilize a bulk temperature. RIB at 215
19. Apple relies on the testimony of one of its engineers, Saahil Mehra, who testified that the
13. 14pple tenes of the testimony of one of the digitation, summation in the testification in the

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"than the Accused Products. Tr. (Sarrafzadeh) at 106:10-21 RDX-7.51C. Dr. Sarrafzadeh submits that because the Accused Products have more LEDs than the rainbow sensors, thicker layers would likely be needed to provide the same level of thermal stability. Tr. (Sarrafzadeh) at 1067:4-13. He relied on testimony from Masimo engineers discussing the thickness of the rainbow sensor boards to support his opinion. <i>Id.</i> at 1068:14-25. Apple cites the testimony of Mr. Diab, who was asked whether Masimo designed the rainbow sensor circuit boards to be "as thin as possible." RX-1200C (Diab Dep. Tr.) at 108:12-15. At the hearing, Mr. Diab testified that whether a mass of is sufficient to stabilize a bulk temperature depends on "how much heat you are pumping into the sensor, and that[] typically has to do with the number of LEDs." Tr. (Diab) at 238:9-14. In consideration of the parties' arguments, the undersigned finds that Complainants have		. Tr. (Sarrafzadeh) at 1065:16-1066:9; RDX-
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Products meet the "thermal mass" limitation. As discussed above, "thermal mass" has been construed to mean a mass that stabilizes a bulk temperature. Complainants have failed to show		In consideration of the parties' arguments, the undersigned finds that Complainants have
construed to mean a mass that stabilizes a bulk temperature. Complainants have failed to show	not show	wn, by a preponderance of the evidence, that
	Product	s meet the "thermal mass" limitation. As discussed above, "thermal mass" has been
temperature stabilization in the Accused Products.	construc	ed to mean a mass that stabilizes a bulk temperature. Complainants have failed to show
	tempera	ture stabilization in the Accused Products.

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Complainants disagree with Dr. Sarrafzadeh	's opinion regarding temperature stabilization, but
they rely only on attorney argument to chara-	cterize
CRB at 142-43.	
	RX-0093C.0009-10.

Mr. Goldberg admitted that he "did not do any tests that address stabilization or normalization." Tr. (Goldberg) at 649:4-11; see also id. at 618:1-21 (disagreeing with Apple's understanding that stabilization and normalization were required for a "thermal mass."). Complainants rely on the fact the Accused Products use a single temperature sensor to determine the wavelengths of the LEDs but as discussed above in the context of claim construction, this is insufficient to prove the existence of a "thermal mass"—during prosecution, for example, the examiner recognized that the Cheung prior art estimated such wavelengths without a "thermal mass." See JX-008 at 363; RX-0406 at 13:20-32. Complainants have failed to present any affirmative evidence of temperature stabilization, and accordingly, they have not met their burden to show that the Accused Products contain a "thermal mass." 104

¹⁰⁴ Complainants also acknowledge that the presence of metallized layers does not show the existence of a thermal mass. *See* CRB at 162 (rejecting argument that "*any* metallized layers in a PCB can be a thermal mass").

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There is further evidence in the record to support a finding of non-infring	ement with
respect to the "thermal mass" limitation. Dr. Mehra testified that	of the PCB in
the Accused Products	
Tr. (Sarrafzadeh) at 1065:15-1066:21; RDX-7.49C; R	OV 0087C · DV
0338C. 105 A preponderance of the evidence does not support a finding that the A	
Products meet the "thermal mass" limitation.	recuseu

3. Element [7B]: "a plurality of light emitting sources, including a substrate of the plurality of light emitting sources, thermally coupled to the thermal mass"

With respect to the "plurality of light emitting sources" limitation, Mr. Goldberg identified 4 sets of 3 LEDs in the Accused Products, which are attached to the of the PCB with thermally conductive epoxy. Tr. (Goldberg) at 618:22-619:9; CDX-0013C.09 (citing CX-0057C; CX-0025C; CX-0198C at 17-18; CX-0199C). Mr. Goldberg further conducted testing to show that the LEDs are thermally coupled to the of the PCB. 620:17-621:15; CDX-0013C.013 (citing CX-0839C; CX-0840C). Apple only disputes infringement with respect to the "thermal mass" within this limitation. *See* CIB at 258-59; RIB at 215-19. Accordingly, the evidence shows that the "plurality of light emitting sources" limitation is met by the Accused Products.

Apple argues that the rainbow® sensors were designed to be the testimony of Mohamed Diab who stated at his deposition: "I think that was one of the requirements." RX-1200C (Diab Dep. Tr) at 108:12-15.

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4. Element [7C]: "the sources having a corresponding plurality of operating wavelengths"

With respect to the "plurality of operating wavelengths" limitation, Mr. Goldberg identified red, green, and infrared LEDs in the Accused Products. Tr. (Goldberg) at 619:10-17; CDX-0013C.010 (citing CX-0057C; CX-0025C). There is no dispute with respect to this limitation. *See* CIB at 259. Accordingly, the evidence shows that the "plurality of operating wavelengths" limitation is met by the Accused Products.

5. Element [7D]: "the thermal mass disposed within the substrate"

With respect to the "thermal mass disposed within the substrate" limitation, Mr. Goldberg identified the within the PCB substrate of the Accused Products. Tr. (Goldberg) at 619:18-620:3; CDX-0013C.011 (citing CX-0105C; CX-0193C). Apple does not dispute that the are disposed within the PCB substrate, but as discussed above, Complainants have not shown that these layers comprise a "thermal mass." *See* CIB at 260-61; RIB at 215-19. Accordingly, the evidence shows that the "disposed within the substrate" limitation is met by the Accused Products, but Complainants have not shown that the Accused Products have a "thermal mass."

6. Element [7E]: "a temperature sensor thermally coupled to the thermal mass"

With respect to the "temperature sensor thermally coupled to the thermal mass" limitation, Mr. Goldberg identified a thermistor near the center of the sensor board of the Accused Products. Tr. (Goldberg) at 620:4-16; CDX-0013C.012 (citing CX-0057C; CX-0025C). He performed testing to show that the thermistor is thermally coupled to the of the PCB. Tr. (Goldberg) at 620:17-621:15; CDX-0013C.013 (citing CX-0839C; CX-0840C). As discussed above, Complainants have not shown that the

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comprise a "thermal mass," although Apple does not dispute that the thermistor is thermally coupled to the See CIB at 261-62; RIB at 215-19. Accordingly, the evidence shows that the "temperature sensor" limitation is met by the Accused Products, but Complainants have not shown that the Accused Products have a "thermal mass."

7. Element [7F]: the temperature sensor "capable of determining a bulk temperature for the thermal mass, the operating wavelengths dependent on the bulk temperature"

cure	red by the thermistor in the Accused Products. CIB at 262-65.	
Surc	ed by the inclinision in the Accused Flodders. CIB at 202-03.	
		-
	Complainants argue that the	
	e samplamana di gue titut ine	

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for the thermal mass that is used to estimate the wavelengths of the LEDs. CIB at 262-65; CRB at 149-54.

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In consideration of the parties' arguments, the undersigned finds that Complainants have
not shown, by a preponderance of the evidence, that the thermistor in the Accused Products
determines a "bulk temperature for the thermal mass." As discussed above in the context of
claim construction, the claimed "bulk temperature" must be a representative temperature for the
thermal mass. Complainants have not shown, however, that the Accused Products have a
"thermal mass" that stabilizes a bulk temperature.
Complainants disagree with
Dr. Sarrafzadeh's conclusion, arguing that the observed temperature variation is "remarkably
uniform" and "very stable." CRB at 145-46. But Complainants' contentions are only attorney
argument, without any expert testimony. See RRB at 128-29. Apple documents contradict
Complainants' contentions,
" RX-0093C.0009-10.

Mr. Goldberg admitted that he did not perform any tests to show whether a thermal mass stabilizes or normalizes a bulk temperature in the Accused Products. Tr. (Goldberg) at 649:4-11. His infringement analysis instead relied on the fact that the "temperature as measured by the

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thermistor is meaningful, and that meaningfulness has to do with being able to use that bulk temperature to determine the operating wavelengths." Tr. (Goldberg) at 624:7-25. This evidence may indicate that the temperature sensor in the Accused Products measures a representative temperature for the LEDs, but it does not show a representative temperature for the "thermal mass." As discussed above in the context of the "thermal mass" limitation, the fact that a temperature is used to determine the operating wavelengths of LEDs is insufficient to prove that the temperature is "a bulk temperature for the thermal mass." The determination of operating wavelengths is a separate requirement of this limitation, ¹⁰⁶ and the examiner recognized that calculation of wavelengths using a representative temperature was known in the prior art. *See* JX-008 at 338 (MASITC_00077663), 363 (MASITC_00077988); RX-04.06 at 13:20-32. Accordingly, in addition to the failure to show that the Accused Products have a "thermal mass," Complainants have failed to show by a preponderance of the evidence that the temperature measured by the thermistor is a "bulk temperature for the thermal mass." ¹⁰⁷

8. Element [7G]: "a detector capable of detecting light emitted by the light emitting sources after tissue attenuation"

With respect to the "detector" limitation, Mr. Goldberg identified four photodiodes in the Accused Products. Tr. (Goldberg) at 625:1-9; CDX-0013C.018 (citing CX-0057C; CX-0025C).



and that Complainants were required to show that one of these measurements is the "bulk temperature." RIB at 224; RRB at 129-30. This non-infringement argument was not raised in Apple's pre-hearing brief, however, and accordingly, it has been waived pursuant to Ground Rule 9.2. See CRB at 153-54.

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Complainants further cite the testimony of Apple witnesses confirming that the photodiodes in the Accused Products detect light that is emitted by the LEDs and attenuated by the user's tissue. See, e.g., CX-0281C (Block Dep. Tr.) at 86:17-87:14; CX-0289C (Mannheimer Dep. Tr.) at 133:2-134:12. There is no dispute with respect to this limitation. See CIB at 265; RIB at 215-19. Accordingly, the evidence shows that the "detector" limitation is met by the Accused Products.

9. Element [7H]: "wherein the detector is capable of outputting a signal usable to determine one or more physiological parameters of a patient based upon the operating wavelengths"

With respect to the "outputting a signal" limitation, Mr. Goldberg identified "PPG signals" described in Apple documents corresponding to the output of the photodiodes, which are used to determine blood oxygen saturation in combination with the wavelength estimates for the LEDs. Tr. (Goldberg) at 625:10-25; CDX-0013C.019 (citing CX-0100C at 5-8; CX-0012C at 21). Complainants further cite the testimony of Apple witnesses confirming that signals from the photodiodes are used to determine blood oxygen saturation. *See*, *e.g.*, CX-0281C (Block Dep. Tr.) at 72:10-73:7; CX-0289C (Mannheimer Dep. Tr.) at 134:14-138:1. There is no dispute with respect to this limitation. *See* CIB at 266; RIB at 215-19. Accordingly, the evidence shows that the "outputting a signal" limitation is met by the Accused Products.

10. Element [9]: "a thermistor"

Claim 9 further requires that the "temperature sensor" of claim 7 is a thermistor. As discussed above in the context of the "temperature sensor" limitation, there is no dispute that the Accused Products have a temperature sensor that is a thermistor. *See* Tr. (Goldberg) at 626:3-16; CDX-0013C.020 (citing CX-0057C at 1-2; CX-0025C at 31). Accordingly, the evidence shows that the "thermistor" limitation of claim 9 is met by the Accused Products.

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As discussed above, because Complainants have not shown by a preponderance of the evidence that the "thermal mass" and "bulk temperature for the thermal mass" limitations of claim 7 are met by the Accused Products, the undersigned finds that the Accused Products have not been shown to infringe claim 9 of the '127 patent.

F. Domestic Industry—Technical Prong

Complainants allege that Masimo's rainbow® sensors practice claim 9 of the '127 patent, relying on the testimony of Mr. Diab and Mr. Goldberg. CIB at 266-74; CRB at 154-60; see Tr. (Diab) at 216:15-226:19; Tr. (Goldberg) at 627:3-635:11. Apple disputes whether the rainbow® sensors meet the limitations requiring a "thermal mass" and a temperature sensor "capable of determining a bulk temperature for the thermal mass," relying on the testimony of Dr. Sarrafzadeh. RIB at 224-32; RRB at 130-36; Tr. (Sarrafzadeh) at 1084:6-1087:12. For the reasons discussed below, the undersigned finds that only some of Masimo's rainbow® sensors have been shown to practice claim 9 of the '127 patent.

1. Domestic Industry Products

Mr. Diab explained that there are two different LED assemblies used in Masimo's rainbow® sensors —early rainbow® sensors dating back to 2005 used in a substrate, and current rainbow® sensors use a . Tr. (Diab) at 216:15-219:5; see Tr. (Goldberg) at 627:4-13; CDX-0013C.021.Apple argues that Complainants have failed to identify the Masimo rainbow® sensors by product number and have failed to specify which products are "early" or "current" rainbow® sensors. RIB at 224-24; RRB at 130-31. Complainants submit that the rainbow® sensors have been identified on a sales spreadsheet. CRB at 9; CX-0649C. Complainants contend that "pre-2009 sales are for early rainbow®

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sensors and later sales are for current rainbow® sensors," citing the testimony of Mr. Diab. CRB at 10 (citing Tr. (Diab) at 216:15-218:1, 220:4-221:10). Mr. Diab testified at the hearing: "My understanding is that . . . we have switched to the in around 2009." Tr. (Diab) at 233:16-20. Masimo's sales spreadsheet (CX-0649C) shows continuous sales of rainbow® sensors from 2008 through 2012, with no indication of distinct product numbers for early rainbow® sensors and current rainbow® sensors. See CX-0649C. The undersigned agrees with Apple that the record lacks any straightforward identification of Masimo's rainbow® sensors, but the sales data, as explained by Mr. Diab's testimony, is sufficient to infer that the design of Masimo's rainbow® sensors was changed in 2009 such that "early" rainbow® sensors before 2009 were comprised of the rainbow® sensors made and sold after 2009 are "current" rainbow® sensors with a

2. Element [7 preamble]: "physiological sensor"

There is no dispute that the early and current rainbow® sensors meet the limitations in the preamble of claim 7, describing "[a] physiological sensor capable of emitting light into tissue and producing an output signal usable to determine one or more physiological parameters of a patient." *See* CIB at 266-67. Mr. Goldberg identified evidence that the rainbow® sensors contain a photodetector that detects light emitted by LEDs and produces a signal that is used to determine "patient measurement values." Tr. (Goldberg) at 627:14-22; CDX-0013C.022 (citing CX-0430C at 5). Accordingly, the evidence shows that the preamble limitations of claim 7 are met by each of the rainbow® sensors.

¹⁰⁸ The parties have stipulated that the preambles of the asserted patent claims are limiting. *See* Joint Stipulation of Facts ¶ 9, EDIS Doc. ID 770692 (May 13, 2022).

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3. Element [7A]: "a thermal mass"

With respect to the "thermal mass" limitation, Complainants rely on different structures in the current rainbow® sensors and the early rainbow® sensors. CIB at 267-69. Mr. Diab described an material that is used in the substrate of the current rainbow® sensors, "because it has very good heat conduction." Tr. (Diab) at 220:4-222:1 (citing CX-0454C; CX-0589C). Mr. Goldberg identified this as the claimed "thermal mass" in the current rainbow® sensors, relying on Masimo documents and Mr. Diab's testimony. Tr. (Goldberg) at 627:23-628:24; CDX-0013C.023 (citing CX-0590C; CX-135C at 81, 98). With respect to the early rainbow® sensors, Mr. Diab identified , which are "connected with . . . through-holes to make sure that there is a good heat conduction throughout the system." Tr. (Diab) at 216:15-219:5 (citing CX-0397C; CX-0588C). Mr. Goldberg identified the as the claimed "thermal mass" in the early rainbow® sensors. Tr. (Goldberg) at 628:25-629:18; CDX-0013C.024 (citing CX-0588C).

Apple argues that Complainants have failed to show that the rainbow® sensors have a "thermal mass." RIB at 226-29, 230-32. Apple submits that Complainants failed to provide any analysis of the thermal properties of the substrate in the current rainbow® sensors or the early rainbow® sensors. *Id.* at 226-279, 230-32 *see* Tr. (Sarrafzadeh) at 1084:22-1085:11 (noting the Mr. Goldberg "did not do any simulation or any other analysis"). Apple contrasts the lack of analysis for the current rainbow® sensors with Mr. Diab's extensive testing and simulation in the development of the early rainbow® sensors. RIB at 227-29. Apple further argues that Mr. Goldberg did not rely on any of Mr. Diab's testing and simulation for his opinions. RRB at 131-35.

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In consideration of the parties' arguments, the undersigned finds that Complainants have shown by a preponderance of the evidence that the early rainbow® sensors had a "thermal mass," but Complainants have failed to show that the current rainbow® sensors meet this limitation. Although Mr. Goldberg's testimony on this limitation did not rely on testing or detailed analysis of the substrates in the rainbow® sensors, his testimony is supported by other evidence in the record, including Masimo documents and Mr. Diab's testimony. In particular, Mr. Diab testified at his deposition that the early rainbow® sensors were designed to have a relatively significant thermal mass. RX-1200C (Diab Dep. Tr.) at 110:7-11. Mr. Diab also described testing and simulations that he performed in the development of the early rainbow® sensors, where he modeled the temperature of the "thermal mass" to observe the relationship between the temperature of the thermistor and the temperature of the LEDs. *Id.* at 121:4-122:3; Tr. (Diab) at 200:17-203:6 (citing CX-0342C). He observed

finding

Id. at 201:19-203:6. Apple argues that these simulations were only performed with a prototype design and not an actual product, RIB at 232 n.32, but Mr. Diab's description of the metal layers in his simulation matches his description of the structure of the early rainbow® sensors, and this is confirmed in the underlying documents. Compare Tr. (Diab) at 201:2-20 to id. at 216:15-218:21; CX-0342C at 6; CX-0588C. Apple argues that the rainbow® sensors have more LEDs than in Mr. Diab's simulations, but Mr. Diab explained that the amount of was designed to account for up to 16 LEDs. RX-1200C (Diab Dep. Tr.) at 110:7-112:1. Mr. Diab further described testing on the early rainbow® sensors where he verified that the wavelength of the LEDs could be accurately determined with an equation using the measured

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temperature, confirming that the actual products work in accordance with his simulations. Tr. (Diab) at 203:7-204:11. Apple has offered no independent testing to refute Mr. Diab's testimony regarding the thermal mass in the early rainbow® sensors. *See* CRB at 156. Accordingly, the undersigned finds that Complainants have shown by a preponderance of the evidence that this limitation is met by the early rainbow® sensors.

The evidence from Mr. Diab's simulations is not applicable to the current rainbow® sensors, however. Mr. Goldberg and Mr. Diab described different structures for the alleged "thermal mass" in the current rainbow® sensors, which have a Tr. (Goldberg) of the current rainbow® sensors at 627:3-13; Tr. (Diab) at 220:25-222:1. The Id. at 221:19-222:1; CX-0598C. Mr. Diab could not find is supplied by a any analysis of temperature stabilization for the Tr. (Diab) at 240:4-11. To show the presence of a "thermal mass," Complainants merely rely on the undisputed fact that the substrate is composed of interconnected metal layers, see Tr. (Goldberg) at 627:23-628:13, and Mr. Diab's testimony that the current rainbow® sensors are tested to verify the accuracy of the calculation of wavelengths for the LEDs. See Tr. (Diab) at 246:7-19. As discussed above in the context of infringement, this is insufficient to prove that this limitation is met. Accordingly, Complainants have failed to show by a preponderance of the evidence that the current rainbow® sensors have a "thermal mass."

4. Element [7B]: "a plurality of light emitting sources, including a substrate of the plurality of light emitting sources, thermally coupled to the thermal mass"

There is no dispute that the early and current rainbow® sensors meet the "plurality of light emitting sources" limitation. *See* CIB at 269-70. Mr. Diab testified that all of Masimo's rainbow® sensors have more than two LEDs. Tr. (Diab) at 211:17-23. He described the

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placement of the LEDs in the early rainbow® sensors, *id.* at 216:15-217:8 (citing CX-0397C), and the current rainbow® sensors. *Id.* at 220:4-24 (citing CX-0454C). Mr. Goldberg identified Masimo documents showing the LEDs attached to the substrate of the rainbow® sensors using "thermally and electrically conductive epoxy." Tr. (Goldberg) at 629:19-630:12; CDX-0013C.025 (citing CX-0454C); CDX-0013C.026 (citing CX-0397C). Accordingly, the evidence shows that the "plurality of light emitting sources" limitation is met by each of the rainbow® sensors, except to the extent that the current rainbow® sensors have not been shown to have a "thermal mass."

5. Element [7C]: "the sources having a corresponding plurality of operating wavelengths"

There is no dispute that the early and current rainbow® sensors meet the "plurality of operating wavelengths" limitation. *See* CIB at 271. Mr. Goldberg cites Masimo schematics showing the multiple wavelengths of light for the LEDs in the rainbow® sensors. Tr. (Goldberg) at 630:13-24; CDX-0013C.027 (citing CX-0454C); CDX-0013C.028 (citing CX-0397C). Accordingly, the evidence shows that the "plurality of operating wavelengths" limitation is met by each of the rainbow® sensors.

6. Element [7D]: "the thermal mass disposed within the substrate"

There is no dispute that the early and current rainbow® sensors meet the "disposed within the substrate" limitation. *See* CIB at 271. Mr. Goldberg identified the between the top and bottom of the substrate in the current rainbow® sensors. Tr. (Goldberg) at 630:25-31:6; CDX-0013C.029 (citing CX-0590C). He identified the between the top and bottom of the substrate in the early rainbow® sensors. Tr. (Goldberg) at 631:9-16; CDX-0013C.030 (citing CX-0588C). Accordingly, the evidence shows that the "thermal mass disposed within the substrate" limitation is met by the early rainbow® sensors,

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and the of the current rainbow® sensors are also "disposed within a substrate," although they have not been shown to be a "thermal mass."

7. Element [7E]: "a temperature sensor thermally coupled to the thermal mass"

There is no dispute that the early and current rainbow® sensors have "a temperature sensor thermally coupled to the thermal mass." *See* CIB at 271. Mr. Goldberg identified a thermistor on the substrate in the current rainbow® sensors and the early rainbow® sensors. Tr. (Goldberg) at 631:17-632:16; CDX-0013C.031 (citing CX-0454C); CDX-0013C.032 (citing CX-0397C). Accordingly, the evidence shows that the "thermally coupled" limitation is met by each of the rainbow® sensors, except to the extent that the current rainbow® sensors have not been shown to have a "thermal mass."

8. Element [7F]: the temperature sensor "capable of determining a bulk temperature for the thermal mass, the operating wavelengths dependent on the bulk temperature"

With respect to the "bulk temperature" limitation, Complainants identify the temperature measured by the thermistor in the rainbow® sensors. CIB at 271-73. Mr. Goldberg identifies Masimo documentation showing that the output from the thermistor in the rainbow® sensors is used "so that adjustments can be made to account for the temperature." Tr. (Goldberg) at 632:17-633:12; CDX-0013C.033 (citing CX-0430C). He further relies on Masimo source code that shows a calculation of wavelengths for the LEDs using the thermistor temperature. Tr. (Goldberg) at 633:13-24; CDX-0013C.034 (citing CPX-0152C; CPX-0151C). His analysis is the same for the early rainbow® sensors and the current rainbow® sensors. Tr. (Goldberg) at 633:25-634:2. Mr. Diab explained that in the development of the early rainbow® sensors, Masimo engineers developed an equation for predicting the wavelength of LEDs using a temperature measurement from a thermistor. Tr. (Diab) at 198:12-200:13. They were able to

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confirm that the equation correctly estimated the wavelengths using a spectrometer. *Id.* at 203:7-204:1. Mr. Diab explained that he wrote "[t]he original code for all of the rainbow [sensors] including the wavelength correction," and the code on the current rainbow® sensors is a "modified version." Tr. (Diab) at 212:21-213:6.

Apple argues that Complainants have not shown that the rainbow® sensors are capable of determining a "bulk temperature," because Mr. Goldberg did not perform any testing on the thermistor or the "thermal mass" in these products. RIB at 229-30; RRB at 135-36.

Dr. Sarrafzadeh offered his opinion that the thermistor in the rainbow® sensors measures a "local temperature" and not a "bulk temperature." Tr. (Sarrafzadeh) at 1086:11-21. Apple further argues that Mr. Goldberg's testimony regarding the determination of operating wavelengths was conclusory. RRB at 136.

In consideration of the parties' arguments, the undersigned finds that Complainants have shown by a preponderance of the evidence that the thermistors in the early rainbow® sensors are capable of measuring a "bulk temperature" that is a representative temperature for the "thermal mass" in the substrate of these products. As discussed above in the context of the "thermal mass" limitation, Mr. Diab described "hundreds of experiments" in simulations for the design of the early rainbow® sensors. Tr. (Diab) at 199:17-200:13 (citing CX-0342C). In those simulations, he observed that

Id. at 201:19-203:6. Mr. Diab also described testing on the early rainbow® sensors where he verified that the wavelength of the LEDs could be accurately determined with an equation using the measured temperature. Tr. (Diab) at 203:7-204:11.

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Apple's arguments primarily rely on Complainants' alleged failure of proof for this limitation—the only affirmative evidence that Apple cites is Dr. Sarrafzadeh's opinion that the thermistor measures a "local temperature" rather than a "bulk temperature." Tr. (Sarrafzadeh) at 1086:11-21. As discussed above in the context of infringement, however, Apple concedes that "a 'bulk temperature' could be measured by a properly positioned single thermistor if the thermal mass were stabilized at the bulk temperature," RRB at 122, and the "bulk temperature" embodiment in the specification is based on a single thermistor. See JX-007 at 10:62-11:4, Fig. 16. Mr. Diab testified that Masimo's design of the early rainbow® sensors was based on the use of a single thermistor after recognizing that it would be difficult Tr. (Diab) at 198:12-199:16. Mr. Diab's testimony further confirms determine the operating wavelengths of LEDs. See Tr. (Diab) at 203:7-204:11. Accordingly, a

that the bulk temperature from the thermistor in the early rainbow® sensors was used to preponderance of the evidence shows that the early rainbow® sensors meet the limitation requiring a temperature sensor to determine a "bulk temperature" for the thermal mass, and the wavelengths of the LEDs are dependent on the bulk temperature.

As discussed above in the context of the "thermal mass" limitation, however, Complainants have not shown that the current rainbow® sensors have a "thermal mass" that stabilizes a "bulk temperature." Complainants did not present any analysis of temperature stabilization on the of the current rainbow® sensors, and accordingly, Complainants have not shown, by a preponderance of the evidence, that the current rainbow® sensors meet the "bulk temperature" limitation.

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9. Element [7G]: "a detector capable of detecting light emitted by the light emitting sources after tissue attenuation"

There is no dispute that the early and current rainbow® sensors have "a detector capable of detecting light emitted by the light emitting sources after tissue attenuation." *See* CIB at 273-74. Mr. Goldberg identified detectors in the rainbow® sensors that detect "modulated LED light, which passes through the tissue." Tr. (Goldberg) at 634:3-635:11; CDX-0013C.035 (citing CX-0440C); CDX-0013C.03 (citing CX-0430C at 2, 5). Accordingly, the evidence shows that the "detector" limitation is met by each of the rainbow® sensors.

10. Element [7H]: "wherein the detector is capable of outputting a signal usable to determine one or more physiological parameters of a patient based upon the operating wavelengths"

There is no dispute that the detector in the rainbow® sensors outputs a signal that is used to determine physiological parameters. *See* CIB at 273-74. Complainants identify a Masimo specification describing the signal from the detectors, stating that "[t]he OEM Board uses this signal to compute patient measurement values." CX-0430C at 5; *see* Tr. (Goldberg) at 634:22-635:11; CDX-0013C.03 (citing CX-0430C at 2, 5). Accordingly, the evidence shows that the "signal usable to determine one or more physiological parameters" limitation is met by each of the rainbow® sensors.

11. Element [9]: "a thermistor"

Claim 9 further requires that the "temperature sensor" of claim 1 is a thermistor. As discussed above in the context of the "temperature sensor" limitation, and there is no dispute that the temperature sensor in the rainbow® sensors is a thermistor. Tr. (Goldberg) at 631:17-632:16; CDX-0013C.031 (citing CX-0454C); CDX-0013C.032 (citing CX-0397C).

Accordingly, the evidence shows that the "thermistor" limitation of claim 9 is met by each of the rainbow® sensors.

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Accordingly, because each limitation of claims 1 and 9 is met, the undersigned finds that Complainants have shown by a preponderance of the evidence that the early rainbow® sensors practice claim 9 of the '127 patent. For the reasons discussed above in the context of the "thermal mass" and "bulk temperature" limitations, Complainants have not shown by a preponderance of the evidence that the current rainbow® sensors practice claim 9 of the '127 patent.

G. Invalidity

Apple contends that claim 9 of the '127 patent is obvious in view of several prior art references. RIB at 233-45; RRB at 136-50. Apple's contentions primarily rely on two references: an article published in 1991 by Yitzhak Mendelson (RX-0458, "Mendelson"); and a Japanese patent application published in 2004 naming inventor Yukio Yamada (RX-0381, "Yamada"). Apple relies on the testimony of Dr. Sarrafzadeh to support its invalidity contentions. Tr. (Sarrafzadeh) at 1046:14-1064:7.

1. Mendelson

Apple contends that claim 9 of the '127 patent is obvious in view of an article entitled "Invasive and Noninvasive Blood Gas Monitoring" authored by Yitzhak Mendelson and published in *Bioinstrumentation and Biosensors* in 1991 (RX-0458 "Mendelson"), in combination with the textbook *Design of Pulse Oximeters* by J.G. Webster, published in 1997 (RX-0035, "Webster"). RIB at 233-39; RRB at 140-46. Mendelson and Webster are both prior art to the '127 patent pursuant to 35 U.S.C. § 102(b). 109

¹⁰⁹ The pre-AIA version of 35 U.S.C. § 102 is applicable to the '127 patent. *See* America Invents Act, 35 USCA § 100 Note, § 3(n)(1), 125 Stat. 284 (Sept. 16, 2011)

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Complainants argue that Apple has not shown claim 9 to be obvious in view of Mendelson and Webster because Mendelson does not disclose the claimed "thermal mass," "thermal mass disposed within the substrate," or a "temperature sensor." CIB at 277-78; CRB at 161-62. Complainants further argue that the combination of Mendelson and Webster fails to meet the "thermal mass" limitations and the limitations requiring a temperature sensor "thermally coupled to the thermal mass and capable of determining a bulk temperature for the thermal mass." CIB at 279-80; CRB at 162-64. Complainants argue that Webster's disclosures are cumulative of U.S. Patent No. 5,259,381 to Cheung (RX-0406, "Cheung"), a prior art patent that was considered during the prosecution of the '127 patent. CIB at 275-76.

a. Element [7 preamble]: "physiological sensor"

There is no dispute that Mendelson meets the limitations of the preamble of claim 7, describing "[a] physiological sensor capable of emitting light into tissue and producing an output signal usable to determine one or more physiological parameters of a patient." See CIB at 277-80; CRB at 161-64. Dr. Sarrafzadeh identified a "noninvasive reflection SaO₂ sensor" disclosed in Mendelson. Tr. (Sarrafzadeh) at 1049:9-13; RX-0458 at 266-71, Fig. 10.16. He described the operation of a pulse oximeter as depicted in Mendelson, where LEDs emit light to the tissue, "and there are a collection of photodiodes that collect the light after it has been through the tissue, and they make a determination of physiological parameters based on the optical light received by the photodiodes." Tr. (Sarrafzadeh) at 1049:14-23.

b. Element [7A]: "a thermal mass"

Apple identifies the ceramic substrate depicted in Mendelsohn as the claimed "thermal mass." RIB at 234-35. Dr. Sarrafzadeh offers his opinion that the circuit board in Mendelsohn would provide thermal connectivity and that one of ordinary skill in the art would have known to

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add a "metal core or thermal core" to provide "thermal management." Tr. (Sarrafzadeh) at 1049:24-1051:12. He references a textbook, *The Multilayer Printed Circuit Board Handbook* by J.A. Scarlett, which describes thermal cores that can be manufactured within substrates for heat conduction. RX-0397.0122 (recognizing that "the popular epoxy fiberglass substrates are notably poor heat conductors and therefore cannot provide a sufficient heat extraction," and describing "an integral heat conductor, i.e., a metal core, within the structure, to alleviate this problem"). Apple also compares Mendelsohn's disclosure of a printed circuit board with Complainants' contentions that the metal layers in the printed circuit boards of the Accused Products and the rainbow® sensors meet the "thermal mass" limitation, arguing that Mendelsohn would meet this limitation for the same reasons. CIB at 234-35; *see* Tr. (Sarrafzadeh) at 1050:25-1051:12.

Complainants argue that Mendelsohn does not disclose a "thermal mass" because there is no disclosure of thermal properties or any description of thermal coupling. CIB at 277-78.

Complainants submit that Dr. Sarrafzadeh failed to provide any testing or simulations of the ceramic substrate in Mendelsohn. *Id.* at 278. Complainants argue that Apple mischaracterizes Mr. Goldberg's infringement and domestic industry analysis, which does not rely on an assumption that every multilayer circuit board contains a "thermal mass"—Complainants submit that Mr. Goldberg relied on evidence of the thermal coupling of components and the fact that the temperature of the board could be used to reliably estimate the operating wavelengths of the LEDs. *Id.* at 277-78. Complainants further argue that Apple should be precluded from relying on Scarlett as an obviousness ground, because it was not identified in Apple's invalidity contentions. *Id.* at 283-84. Even if Scarlett's disclosures were considered, Complainants submit that Apple failed to identify any reason to add a thermal core to Mendelsohn. CRB at 161.

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Dr. Goldberg testified that the problem of heat removal addressed in Scarlett is different from the use of a "thermal mass" to facilitate a bulk temperature measurement. Tr. (Goldberg) at 1398:9-1399:8.

In consideration of the parties' arguments, the undersigned finds that Apple has not shown, by clear and convincing evidence, that Mendelsohn discloses a "thermal mass." The pulse oximeter depicted in Mendelsohn has a "ceramic substrate," but there is no description of the thermal characteristics of this substrate or any components thereon. *See* RX-0458 at 269-71. Dr. Sarrafzadeh's analysis of this element also contains no description of the thermal characteristics of Mendelsohn's substrate. *See* Tr. (Sarrafzadeh) at 1049:24-1052:2. Moreover, it is not clear that the addition of a metal core designed for heat removal in Scarlett would stabilize a bulk temperature, as required for the "thermal mass" limitation—neither Scarlett nor Mendelsohn describe such stabilization. *See* Tr. (Goldberg) at 1398:9-1399:8.

Apple has also failed to identify any clear reason for one of ordinary skill in the art to modify Mendelsohn to add a "thermal mass," merely relying on Dr. Sarrafzadeh's testimony that thermal cores were "known for many years," pointing to a description of a thermal core in Scarlett. ¹¹⁰ *Id.* (citing RX-0397 at 122). Dr. Sarrafzadeh suggests that adding a thermal core to Mendelsohn would provide "for better management," relying on disclosures in Scarlett. Tr. (Sarrafzadeh) at 1051:1-12. In particular, Scarlett describes the problem of "heat removal from tightly packaged components" on "epoxy fiberglass substrates," which can be addressed "[w]ith

¹¹⁰ Complainants argue that Apple should be precluded from relying on Scarlett because no such combination was identified in Apple's invalidity contentions. CIB at 283-84. This argument was previously rejected in the context of Complainants' motion *in limine* no. 2, however, where Apple was allowed to present evidence relying on Scarlett and other prior art references in accordance with the arguments in its prehearing brief. *See* Order No. 40 at 2 (Jun. 1, 2022). Accordingly, Apple will not be precluded from relying on Scarlett in the context of its obviousness arguments.

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an integral heat conductor, i.e., a metal core." RX-0397 at 122. It is not clear that "heat removal" is the same as temperature stabilization, however, and it is not clear that one of ordinary skill in the art would have been motivated to add a metal core to Mendelsohn for the purpose of temperature stabilization or heat removal. Dr. Sarrafzadeh's testimony that a metal core would be added for "better management" is the type of conclusory opinion that has been found to be insufficient to establish a motivation to combine. See ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc., 694 F.3d 1312, 1328 (Fed. Cir. 2012) (where expert testified that a motivation to combine would have been "to build something better," the court found that "[t]his testimony is generic and . . . fails to explain why a person of ordinary skill in the art would have combined elements from specific references in the way the claimed invention does").

Accordingly, Apple has failed to show by clear and convincing evidence that one of ordinary skill in the art would have modified the device in Mendelsohn to add a "thermal mass."

c. Element [7B]: "a plurality of light emitting sources, including a substrate of the plurality of light emitting sources, thermally coupled to the thermal mass"

There is no dispute that Mendelsohn discloses a device with a plurality of LEDs thermally coupled to a circuit board. *See* RIB at 235; CIB at 277-79. Dr. Sarrafzadeh identified red and infrared LEDs shown on a circuit board in Mendelsohn. Tr. (Sarrafzadeh) at 1052:3-8; RDX-7.20.

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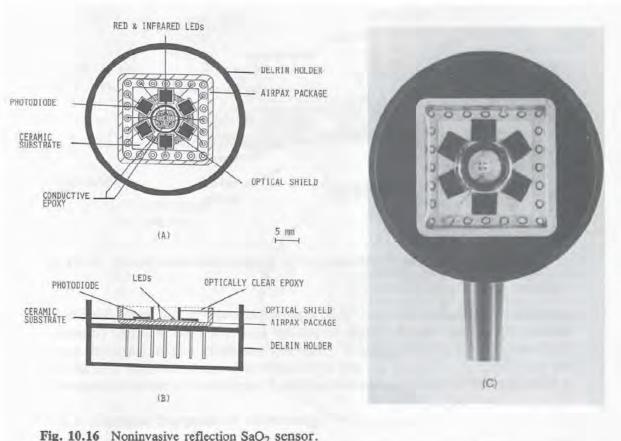


Fig. 10.16 Noninvasive reflection SaO2 sensor.

RX-0458.0024 at Fig. 10.16; see also RX-0458.0022 ("The basic optical sensor of a noninvasive pulse oximeter consists of a light source (typically, a pair of red and infrared LEDs) and a photodetector mounted inside a spring-loaded clip."). Dr. Sarrafzadeh explained that "[b]ecause of electrical connection, we know that the LEDs are connected by wires to the printed circuit board, and that's the thermal connection." Tr. (Sarrafzadeh) at 1052:9-13.

Element [7C]: "the sources having a corresponding plurality of d. operating wavelengths"

There is no dispute that the LEDs in Mendelsohn have two different wavelengths. See RIB at 236; CIB at 277-79. Dr. Sarrafzadeh explains that Mendelsohn describes "red and infrared LEDs." Tr. (Sarrafzadeh) at 1052:18-22; RDX-7.21; RX-0458.0024 at Fig. 10.16; see also RX-0458.0022 (describing "a pair of red and infrared LEDs").

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e. Element [7D]: "the thermal mass disposed within the substrate"

Apple argues that the "thermal mass disposed within the substrate" limitation is obvious in view of Mendelsohn for the same reasons that as the "thermal mass" limitation. *See* RIB at 236; Tr. (Sarrafzadeh) at 1053:1-7. For the reasons discussed above in the context of the "thermal mass" limitation, the undersigned finds that Apple has not shown that "the thermal mass disposed within the substrate" is disclosed in Mendelsohn or that one of ordinary skill in the art would have modified the device in Mendelsohn to add a "thermal mass."

f. Element [7E]: "a temperature sensor thermally coupled to the thermal mass"

Mendelsohn does not disclose a temperature sensor in its pulse oximetry device, but

Apple argues that it would have been obvious to incorporate a temperature sensor in this device

based on disclosures in Webster. RIB at 236-37. Dr. Sarrafzadeh identifies Webster's disclosure

of a temperature sensor as a way to compensate for LED temperature changes that can affect

pulse oximetry measurements. Tr. (Sarrafzadeh) at 1053:8-22; RDX-7.23. Webster explicitly

states: "One way to compensate for LED temperature changes is to have a temperature sensor

built into the probe along with the LEDs and photodiode." RX-0035.085. Dr. Sarrafzadeh

explains that such a temperature sensor would have been electrically connected and thus

thermally coupled to the LEDs and the circuit board of the device in Mendelsohn. Tr.

(Sarrafzadeh) at 1053:8-22. Complainants dispute the alleged obviousness of a "temperature

sensor" as disclosed in Webster, but their arguments appear to be directed to the "thermal mass"

limitation and the "bulk temperature" limitation. CIB at 280; CRB at 162. There does not

appear to be any dispute that Webster explicitly discloses a reason for incorporating a

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temperature sensor in a pulse oximeter and that one of ordinary skill in the art would have expected success in doing so.

g. Element [7F]: the temperature sensor "capable of determining a bulk temperature for the thermal mass, the operating wavelengths dependent on the bulk temperature"

With respect to the "bulk temperature" limitation, Apple cites Webster's recognition that "a shift in LED peak wavelength due to a change in temperature can cause erroneous SpO2 readings." RX-0035.085. Webster provides a solution to this problem: "One way to compensate for LED temperature changes is to have a temperature sensor built into the probe along with the LEDs and photodiode." *Id.* Webster further explains that "[t]emperature information is fed back to the microprocessor, which then estimates how much the peak wavelength of each LED has changed from its rated value." Id. Although Webster only describes one temperature sensor, Dr. Sarrafzadeh suggests that "one of ordinary skill in the art would know that . . . in order to get the bulk temperature in multiple locations, you would just add multiple temperature sensors of Webster." Tr. (Sarrafzadeh) at 1053:23-1054:11. He further testifies that the relationship between wavelength and temperature described in Webster is "a fact of physics that has been known for many years." *Id.* at 1054:20-1055:3. Apple argues that the single temperature sensor in Webster is similar to the single temperature sensor in the Accused Products, and if these products measure a "bulk temperature" then this limitation should also be met by Webster. RIB at 237; see Tr. (Sarrafzadeh) at 1054:14-19.

Complainants argue that Webster's disclosure of a temperature sensor relies on Cheung (RX-0406), which was considered during the prosecution of the '127 patent. CIB at 280, 275-76. Complainants further argue that Mendelson does not disclose a thermal mass, and that Apple does not rely on Webster as disclosing a thermal mass. *Id.* at 279-80.

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In consideration of the parties' arguments, the undersigned finds that Apple has not shown, by clear and convincing evidence, that Webster discloses a temperature sensor capable of determining a "bulk temperature for the thermal mass." Webster does not describe a "thermal mass"—the temperature sensor is "built into the probe" and it is designed to estimate the temperature of the LEDs—not a "bulk temperature for the thermal mass." RX-0035.085. 111

Dr. Sarrafzadeh suggests that one of ordinary skill in the art would have added multiple sensors to obtain an average temperature, Tr. (Sarrafzadeh) at 1054:23-1054:7, but this opinion is not grounded in any prior art disclosure. 112 There is no clear disclosure of a measurement of a "bulk temperature for the thermal mass" in Webster.

h. Element [7G]: "a detector capable of detecting light emitted by the light emitting sources after tissue attenuation"

There is no dispute that Mendelsohn discloses photodiodes that are capable of detecting light from its LEDs after being attenuating by the user's tissue. *See* RIB at 238; CIB at 277-79. These photodiodes are depicted on Figure 10.16 in Mendelsohn. RX-0458.0024; *see* Tr. (Sarrafzadeh) at 1055:4-8.

i. Element [7H]: "wherein the detector is capable of outputting a signal usable to determine one or more physiological parameters of a patient based upon the operating wavelengths"

With respect to the "outputting a signal" limitation, Dr. Sarrafzadeh identified a block diagram (Fig. 10.12) in Mendelsohn depicting an ear oximeter that includes a processor and an output to a digital display. Tr. (Sarrafzadeh) at 1055:11-18; RX-0458.021. Complainants do not

 $^{^{111}}$ Webster notes the potential "difference between the sensed temperature and the actual temperature of the p-n junctions of the LEDs." RX-0035.085.

¹¹² Webster teaches away from the addition of multiple sensors or other components: "In addition, the sensor and additional wires needed will add cost to the probes, making a cost-benefit analysis of this method necessary before its inclusion in a pulse oximeter design." RX-0035.086.

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dispute that Mendelsohn discloses a detector meeting this limitation but argues that Dr. Sarrafzadeh incorrectly identified Mendelsohn's ear oximeter as a pulse oximeter. CIB at 278-79; CRB at 164.

j. Element [9]: "a thermistor"

Claim 9 further requires that the "temperature sensor" of claim 1 is a thermistor.

Complainants argue that a thermistor is not disclosed in Mendelsohn or in Webster. CIB at 278, 280. Apple relies on Dr. Sarrafzadeh's testimony that thermistors "have been known for many years as a resistive circuit." Tr. (Sarrafzadeh) at 1055:19-1056:1. Apple cites a 2003 technical dictionary describing a "thermistor," RX-0419, and a thermistor in a pulse oximeter disclosed in Yamada. RX-0381 at ¶ [0111]. As discussed below, Yamada's disclosure shows that thermistors were known in the prior art and could be used in pulse oximeters.

As discussed above, Apple has not shown by clear and convincing evidence that claim 9 of the '127 patent is obvious in view of Mendelsohn in combination with Webster, because these references fail to disclose a "thermal mass" or the measurement of a "bulk temperature for the thermal mass," and Apple has not shown that it would have been obvious for one of ordinary skill in the art to add these elements.

2. Vamada

Apple contends that claim 9 of the '127 patent is obvious in view of Japanese Patent Application Publication No. 2004-337605A, entitled "Light Probe, Measuring System Using the Same, and Reflected Light Detecting Method Using the Same," naming inventor Yukio Yamada (RX-0381, "Yamada"), in combination with U.S. Patent No. 5,334,916, entitled "Apparatus and Method for LED Mission Spectrum Control, naming inventor Masahiro Noguchi (RX-0353,

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"Noguchi"). RIB at 239-43; RRB at 146-48. Yamada was published on December 2, 2004, and Noguchi issued on August 2, 1994. RX-0381; RX-0353. Yamada and Noguchi are prior art to the '127 patent pursuant to 35 U.S.C. § 102(b). 113

Complainants argue that Apple has not shown claim 9 to be obvious in view of Yamada and Noguchi because these references fail to disclose the claimed "thermal mass" and the limitations requiring a temperature sensor "thermally coupled to the thermal mass and capable of determining a bulk temperature for the thermal mass." CIB at 280-83; CRB at 164-67.

a. Element [7 preamble]: "physiological sensor"

There is no dispute that Yamada meets the limitations of the preamble of claim 7 by describing a pulse oximeter, which is "[a] physiological sensor capable of emitting light into tissue and producing an output signal usable to determine one or more physiological parameters of a patient." *See* RIB at 239; CIB at 280-82; Tr. (Sarrafzadeh) at 1058:2-7; RDX-7.33C; RX-0381 at ¶ 0041, Fig. 1, Fig. 5.

b. Element [7A]: "a thermal mass"

With respect to the "thermal mass" limitation, Dr. Sarrafzadeh identifies Yamada's disclosure of LEDs and photodetectors mounted on a printed circuit board with electrical connections, wherein "the wires provide thermal connectivity." Tr. (Sarrafzadeh) at 1058:8-19. Dr. Sarrafzadeh testified that a person of ordinary skill in the art "would know that you can readily implement this in a multilayer fashion, also add thermal cores in order to provide better thermal management in the circuit." *Id.* Apple argues that Complainants have accused a similar multilayer printed circuit board of meeting this limitation in the context of infringement. RIB at 239-40; RRB at 146-47.

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¹¹³ See supra n.109.

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Complainants argue that Yamada does not disclose a "thermal mass" because there is no description of the structure or thermal properties of Yamada's substrate. CIB at 281.

Complainants submit that Dr. Sarrafzadeh's testimony is insufficient to show that Yamada's circuit board is a "thermal mass." *Id.* Mr. Goldberg testified that Yamada does not disclose a thermal mass "which stabilizes and normalizes in a manner that allows the bulk temperature as measured by the temperature sensor." Tr. (Goldberg) at 1396:22-1397:8. Complainants note that Yamada discloses a "thermal conductor" that "is able to adequately disperse heat from" Yamada's LED to the exterior. RX-0381 at ¶¶ 101-102. Complainants argue that this heat dispersal is different from the use of a thermal mass to stabilize a bulk temperature for measurement. CRB at 165-166; *see* Tr. (Goldberg) at 1398:9-1399:8.

In consideration of the parties' arguments, the undersigned finds that Apple has not shown, by clear and convincing evidence, that Yamada discloses a "thermal mass." For the same reasons discussed above in the context of Mendelsohn, Apple has failed to show that the circuit board in Yamada is a "thermal mass" and has failed to show that one of ordinary skill in the art would have modified Yamada to incorporate a "thermal mass." In particular, Apple has failed to identify any disclosure in Yamada that describes the stabilization of temperatures on its circuit board, and Dr. Sarrafzadeh's testimony with respect to modifying Yamada was conclusory and unsupported by disclosures in the prior art. Apple failed to identify any clear evidence that one of ordinary skill in the art would have modified Yamada to provide temperature stabilization—Yamada discloses a "thermal conductor" that "is able to adequately disperse heat," RX-0381 at \$\frac{1}{3}\$ 101-102, without any discussion of temperature stabilization and no identified need for additional thermal management.

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c. Element [7B]: "a plurality of light emitting sources, including a substrate of the plurality of light emitting sources, thermally coupled to the thermal mass"

There is no dispute that Yamada discloses a plurality of LEDs mounted on a substrate.

See RIB at 240-41; CIB at 280-82. Dr. Sarrafzadeh identified two LEDs electrically and thermally connected to the circuit board in Yamada. Tr. (Sarrafzadeh) at 1058:20-1059:6; RDX-7.35C; RX-0381 at ¶ [0043], Fig. 5.

d. Element [7C]: "the sources having a corresponding plurality of operating wavelengths"

There is no dispute that the LEDs in Yamada have two different wavelengths. *See* RIB at 241; CIB at 280-82. Dr. Sarrafzadeh identifies disclosures in Yamada describing wavelengths of red light and infrared light. Tr. (Sarrafzadeh) at 1059:10-16; RDX-7.36C; RX-0381 at ¶ [0043] ("The light a first wavelength may be, for example, red light with a wavelength near 660 [nm]. . . The light of a second wavelength may be, for example, near infrared light with a wavelength near 880 [nm].").

e. Element [7D]: "the thermal mass disposed within the substrate"

Apple argues that the "thermal mass disposed within the substrate" limitation is obvious in view of Yamada for the same reasons that as the "thermal mass" limitation. See RIB at 241; Tr. (Sarrafzadeh) at 1059:18-25. For the reasons discussed above in the context of the "thermal mass" limitation, the undersigned finds that Apple has not shown that "the thermal mass disposed within the substrate" is disclosed in Yamada or that one of ordinary skill in the art would have modified Yamada to add a "thermal mass."

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f. Element [7E]: "a temperature sensor thermally coupled to the thermal mass"

With respect to the "temperature sensor" limitation, Apple points to Yamada's disclosure that "a temperature sensor maybe be attached to the light probe . . . to the surface of the substrate." RX-0381 at ¶ [0109]. Dr. Sarrafzadeh explains that this temperature sensor would be electrically attached and thus thermally coupled to the alleged "thermal mass." Tr. (Sarrafzadeh) at 1060:1-7; RDX-7.38C. Complainants dispute Yamada's disclosure of a "temperature sensor," but their arguments appear to be directed to the "thermal mass" limitation and the "bulk temperature" limitation. CIB at 281-82; CRB at 165. There does not appear to any dispute that Yamada explicitly discloses that a temperature sensor may be attached to the substrate.

g. Element [7F]: the temperature sensor "capable of determining a bulk temperature for the thermal mass, the operating wavelengths dependent on the bulk temperature"

With respect to the "bulk temperature" limitation, Apple cites Yamada's disclosure of a temperature sensor attached to the light probe on the surface of the LED substrate. RIB at 241; Tr. (Sarrafzadeh) at 1060:8-17. Apple argues that Yamada's temperature sensor meets the "bulk temperature" limitation under the same theory that Complainants have asserted for infringement of this limitation. CIB at 242. Dr. Sarrafzadeh explains that the relationship between the temperature of an LED and its wavelength is a property of physics that would have been known to persons of ordinary skill in the art, and an equation defining this relationship is explicitly described in Noguchi. Tr. (Sarrafzadeh) at 1060:25-1061:9; RDX-7.40C; RX-0353 at 2:59-68. Noguchi describes "a temperature measurement means for measuring the temperature of an LED or for measuring the temperature in the environment in which the LED is disposed," adding that "[a] plurality of LEDs and a plurality of temperature measurement means can be utilized in the present invention." RX-0353 at 1:38-50. Dr. Sarrafzadeh testified that one of ordinary skill in

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the art would have known from the teaching in Noguchi that a temperature measurement could be used to provide better wavelength estimation for the pulse oximeter in Yamada. Tr. (Sarrafzadeh) at 1061:10-1062:8. He explains that using Noguchi's wavelength estimation would have improved the functioning of Yamada's pulse oximeter and that this functionality would have been "easily added" by one of ordinary skill in the art. Id.

Complainants argue that the temperature sensor in Yamada does not measure a "bulk temperature." CIB at 281-82. Mr. Goldberg testified that Yamada's temperature sensor is only configured to detect "when the temperature gets too high for safety reasons," and not to measure a bulk temperature that "can be used for reliably estimating LED operating wavelengths." Tr. (Goldberg) at 1396:22-1397:8 (citing RX-0381 at ¶ [111]). Complainants note that Yamada discloses a "thermal conductor" for heat dispersal rather than to stabilize a bulk temperature for measurement. CRB at 165-166 (citing RX-0381 at ¶¶ 101-102); see Tr. (Goldberg) at 1398:9-1399:8. Complainants argue that Noguchi does not measure a "bulk temperature" for estimating wavelengths for multiple LEDs but merely discloses measuring the temperature of an LED to measure the wavelength for that LED. CIB at 283; CRB at 166-67; Tr. (Goldberg) at 1397:9-21. Complainants argue that Apple has failed to show a motivation to combine Yamada and Noguchi with an expectation of success. CRB at 167.

In consideration of the parties' arguments, the undersigned finds that Apple has not shown, by clear and convincing evidence, that Yamada in combination with Noguchi discloses a temperature sensor capable of determining a "bulk temperature for the thermal mass." Yamada does not disclose a measurement of temperature for a "thermal mass"—the temperature sensor is placed "to measure the temperature near the user" to "take action when the temperature gets too high, for example by sounding an alarm or halting light emission from the light-emitting

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component." RX-0381 at ¶ 0901-0111. Noguchi similarly fails to disclose a measurement of temperature for a "thermal mass"—similar to Webster's disclosures discussed above, Noguchi describes the relationship between an LED's temperature and its operating wavelength, see RX-0353 at 1:38-50, 2:58-60, but Noguchi fails to disclose the measurement of a "bulk temperature for the thermal mass." Noguchi does not describe the use of a single representative temperature for a "thermal mass" but instead suggests direct temperature measurements of individual LEDs, describing "[a] plurality of LEDs and a plurality of temperature means." RX-0353 at 1:48-50. Dr. Sarrafzadeh's suggestion to average the readings from multiple temperature sensors to generate a "bulk temperature" is conclusory and is not supported by disclosures in the prior art. See Tr. (Sarrafzadeh) at 1060:8-16. Apple has not shown that any measurement of a "bulk temperature" is disclosed in Yamada or Noguchi, or that such a measurement would have been known to persons of ordinary skill in the art.

h. Element [7G]: "a detector capable of detecting light emitted by the light emitting sources after tissue attenuation"

There is no dispute that Yamada discloses a detector that receives light from the LEDs after tissue attenuation. See RIB at 243; CIB at 280-82. Yamada explicitly discloses that "[a] portion of the light that traversed body tissue is received by the light-receiving component 12." RX-0381 at ¶ 0062; see Tr. (Sarrafzadeh) at 1062:9-14.

i. Element [7H]: "wherein the detector is capable of outputting a signal usable to determine one or more physiological parameters of a patient based upon the operating wavelengths"

There is no dispute that the detector in Yamada is used to determine blood oxygen saturation based on the ratio of the fluctuation ranges of red and infrared light. See RIB at 243; CIB at 280-82. Yamada explicitly discloses that "a strength signal for the light is sent to the analysis component 2 in the form of an electrical signal," and "analysis component 2 determines

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the range of fluctuation in the strength signal at each wavelength The CPU 23 then searches the memory component 25 for the numerical value of the oxygen concentration level corresponding to the ratio of the fluctuation ranges, and outputs the result of the search." RX-0381 at ¶ 0062, 0065; see Tr. (Sarrafzadeh) at 1062:15-24.

j. Element [9]: "a thermistor"

Claim 9 further requires that the "temperature sensor" of claim 1 is a thermistor. There is no dispute that Yamada discloses the use of a thermistor as its temperature sensor. *See* RIB at 243; CIB at 280-82. Yamada explicitly provides examples of temperature sensors: "it is possible to use a thermistor, a metal resistance temperature detector, or a thermocouple as the temperature sensor." RX-0381 at ¶ 0111; *see* Tr. (Sarrafzadeh) at 1062:21-25.

For the reasons discussed above, Apple has not shown by clear and convincing evidence that claim 9 of the '127 patent is obvious in view of Yamada in combination with Noguchi, because these references fail to disclose a "thermal mass" or the measurement of a "bulk temperature for the thermal mass," and Apple has not shown that it would have been obvious for one of ordinary skill in the art to add these elements.

3. Objective Indicia of Non-Obviousness

Complainants identify evidence of commercial success and industry praise for Masimo's rainbow® sensors that support a finding of non-obviousness. CIB at 285-87. Masimo's financial records show that Masimo has earned in revenue from the sale of rainbow® sensors practicing claim 9 of the '127 patent, with a growth rate of from 2008 through 2014. Tr. (McGavock) at 1426:9-1427:7; CDX-0019C.0012 (citing CX-0649C). Complainants further cite evidence that the rainbow® sensors have won numerous awards,

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Innovation and Support, and the 2006 American Electronics Association Innovative Medical
Technology Award. CX-1378 at 62-68. In connection with a 2006 award from the Society for
Technology in Anesthesia, a study of a rainbow® sensor product found that the "technology
represents a major advance in the monitoring of oxygenation." *Id.* at 69. Mr. Goldberg testified
that the success of the rainbow® sensor products "obviously depended on them functioning to do
what they were meant to do, which was to measure a variety of physiological parameters in a
manner that hadn't been done before," and the patented features were

Tr. (Goldberg) at 1400:9-1401:18.¹¹⁴ Apple argues that Complainants failed to show a nexus between the invention of the '127 patent and the alleged commercial success and industry praise, criticizing Mr. Goldberg's testimony as conclusory. CRB at 149.

In consideration of the parties' arguments, the undersigned finds that the evidence of commercial success and industry praise for the early rainbow® sensor products is consistent with the findings of nonobviousness with respect to claim 9 of the '127 patent, although Complainants' evidence for nexus is weak. There is no explicit praise for the temperature-based wavelength correction in the early rainbow® sensor products, but Complainants did present testimony from Mr. Diab that the

¹¹⁴ Complainants also identify evidence of teaching away, CIB at 287, but this evidence has been considered in the context of the *prima facie* case for obviousness with respect to the "bulk temperature" limitation allegedly disclosed in Webster. *See supra*, n.111, n.112.

¹¹⁵ These secondary considerations are only relevant with respect to the early rainbow® sensors that have been found to practice claim 9 of the '127 patent. Accordingly, any post-2009 commercial success is not relevant to obviousness.

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Tr. (Diab) at 204:2-11. This evidence shows that there may be some nexus between the invention of the '127 patent and the commercial success and industry praise for the early rainbow® sensor products, although inventor testimony is not the type of "objective" evidence that is generally considered by the Federal Circuit. *Cf. Arkie Lures, Inc. v. Gene Larew Tackle, Inc.*, 119 F.3d 953, 957 (Fed. Cir. 1997) ("The so-called "secondary considerations" provide evidence of how the patented device is viewed by the interested public: not the inventor, but persons concerned with the product in the objective arena of the marketplace."). Accordingly, the evidence of commercial success and industry praise for the early rainbow® sensor products is not entitled to significant weight, but it is consistent with the findings of nonobviousness above with respect to claim 9 of the '127 patent.

VII. DOMESTIC INDUSTRY – ECONOMIC PRONG (MASIMO WATCH)

With respect to the Poeze patents and the '745 patent, Masimo relies on "Masimo Watch" products to satisfy the domestic industry requirement, including certain prototypes that were developed between 2019 and 2021, and a final product that was manufactured in December 2021. See CIB at 26-35, 288-309.

A. The "Masimo Watch" Articles

The earliest "Masimo Watch" prototype identified in this investigation is the "Circle sensor" (CPX-0021C), which "would have been built in October 2019," according to Masimo engineer Stephen Scruggs. Tr. (Scruggs) at 394:12-18. Masimo's next domestic industry product is the "Wings sensor" (CPX-0029C), which "would have been built in January of 2020." *Id.* at 395:7-15. Both the Circle sensor and Wings sensor relied on an external device to calculate oxygen saturation, but in November 2020, Masimo built the "RevA sensor" (CPX-

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0052C), "which included onboard processing." *Id.* at 396:2-13. Then in April 2021, Masimo added a display for the "RevD sensor" (CPX-0058C). *Id.* at 397:7-24. Between May and September 2021, during the time the complaint was filed, Masimo developed the "RevE sensors" (CPX-0019C, CPX-0020C, CPX-0065C), which included certain changes to the emitters and photodiodes of the "RevD sensor." Tr. (Scruggs) at 398:1-23. 116

B. Disputed Background Issues Regarding Domestic Industry Investments

As preliminary issues, the parties dispute (1) whether the investments in "Masimo Watch" products can be aggregated for the economic prong analysis; and (2) whether Masimo's pre-2018 investments regarding wrist-worn sensors should be considered. *See* RIB at 249-50, 256-57, 267-68; RRB at 155, 164; CIB at 301-05; CRB at 179-80. Each of these disputes is addressed below.

1. Aggregation of "Masimo Watch" Expenditures

Complainants have not separately accounted for domestic industry expenditures with respect to each Masimo Watch prototype, relying on Masimo's aggregate investments because the prototypes were part of a continuous design and development effort towards a commercial product. CIB at 300-301 (citing Tr. (Muhsin) at 342:25-343:7 (describing "many iterations of wrist sensors"), 345:2-7 (describing "[m]any iterations on the watch through the design phases"); Tr. (Scruggs) at 393:12-20 ("we've designed, built, and tested many iterations of the Masimo Watch"), 402:2-12 (describing "the progression of the different sensor designs").

¹¹⁶ Complainants also rely on the Masimo W1 as a domestic industry product, but for the reasons discussed *supra* in the context of the technical prong, evidence regarding this product will not be considered.

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Apple argues that it was improper for Complainants to aggregate the Masimo Watch expenditures. RIB at 256-57. Apple cites *Certain Electronic Stud Finders, Metal Detectors, And Electrical Scanners*, where the Commission held that "aggregating investments in different domestic products that practice different patents effectively precludes the Commission from quantifying the amounts of the investments in each statutory category and determining the significance" of such investments. Inv. No. 337-TA-1221, Comm'n Op. at 48, EDIS Doc. ID 765331 (Mar. 14, 2022) ("*Electronic Stud Finders*").

In consideration of the parties' arguments, the undersigned finds that Masimo's investments in the development of Masimo Watch prototypes can be aggregated for the economic prong analysis. The record shows continuous development of such prototypes at Masimo—unlike the different products at issue in *Electronic Stud Finders*, the evidence indicates that the Masimo Watch prototypes are merely "iterations" of a product design that was continuously developed in the years leading up to the filing of the complaint. See Tr. (Muhsin) at 342:25-343:7, 345:2-7; Tr. (Scruggs) at 393:12-20, 402:2-12; Tr. (Al-Ali) at 275:13-276:11. The Circle sensor was built in October 2019, the Wings sensor in January 2020, the RevA sensor in November 2020, the RevD sensor in April 2021, and the RevE sensors between May and September 2021. See Tr. (Scruggs) at 394:12-18, 395:7-15, 396:2-13, 397:7-24, 398:1-23. Within such a development timeline, there is no reasonable way to delineate between work on separate prototypes—research and development activities within the Masimo Watch project between January 2020 and November 2020 are likely to involve both improvements to the Wings sensor and development of new features for the RevA sensor. Masimo's CFO, Micah Young, explained that Masimo's financial records did not track expenditures at this level of detail. See Tr. (Young) at 48:22-25.

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With respect to the '745 patent, aggregation of the domestic industry expenditures is clearly appropriate because each of the identified prototypes has been found to practice claim 18 of the '745 patent. 117 Complainants have not asserted that the Circle sensor or the Wings sensor practice claims of the Poeze patents, but the record shows that the development of these prototypes led to the development of the RevA, RevD, and RevE prototypes that Complainants have asserted as domestic industry products for the Poeze patents. *See* Tr. (Scruggs) at 394:12-398:23. Accordingly, the undersigned finds that Masimo's pre-complaint investments in all of the identified prototype Masimo Watch products can also be considered as part of the domestic industry for the Poeze patents and the '745 patent. The evidence shows that Masimo's investment in the development of these prototypes occurred in the most relevant timeframe for determining whether the domestic industry requirement has been satisfied—*i.e.*.., the time period leading up to the date the complaint was filed in July 2021.

2. Masimo's Pre-2018 Investments

Complainants have identified over in in investments in research and development related to "wrist-worn parameter monitoring" dating back to 2001 and continuing up to 2018. CIB at 305; CRB at 179-80. Complainants submit that these research and development activities were "foundational" to the development of the Masimo Watch. CRB at 179-80. Apple argues that these investments pre-date any of the identified Masimo Watch prototypes and cannot be reasonably attributed to the asserted domestic industry articles. RIB at 249-50, 267-68; RRB at 155, 164.

¹¹⁷ Although the record is not clear as to whether the Circle sensor and Wings sensor were connected to the identified Rad-97 monitor before the filing of the complaint for satisfaction of the technical prong, there is evidence that these sensors were used with some external monitors to measure blood oxygen, *see* Tr. (Scruggs) at 403:11-404:2, and investments in these prototypes are thus "with respect to articles protected by" the '745 patent.

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In consideration of the parties' arguments, Masimo's pre-2018 expenditures will be excluded from the domestic industry analysis. There is no specific evidence in the record describing Masimo's "wrist-worn" research and development activities, and Complainants have provided no clear explanation of the relationship between these activities and the identified Masimo Watch prototypes. *See* Tr. (Kiani) at 115:1-122:21. The Commission has held that merely identifying expenditures with respect to general product lines is not sufficient to account for expenditures "with respect to" domestic industry articles. *See Certain Digital Media Devices, Including Televisions, Blu-Ray Disc Players, Home Theater Systems, Tablets and Mobile Phones, Components Thereof and Associated Software*, Inv. No. 337-TA-882, Final Initial Determination at 449-51, EDIS Doc. ID 539707 (July 7, 2014) (finding that investments that "are linked to broad product categories rather than to specific products" do not "form an adequate basis for a determination that a domestic industry exists"), *not reviewed in relevant part by* Comm'n Notice, EDIS Doc. ID 541887 (Sept. 11, 2014). Accordingly, Masimo's pre-2018 expenditures will not be considered as part of the domestic industry analysis.

C. Domestic Industry Existing at the Time of the Complaint

As discussed above in the context of the technical prong of the domestic industry requirement for the Poeze patents and the '745 patent, *supra* Section IV.F.7, Section V.F.2, Complainants have shown that Masimo Watch prototypes practicing claim 12 of the '501 patent, claim 28 of the '502 patent, claims 12, 24, and 30 of the '648 patent, and claim 18 of the '745 patent existed at the time of the filing of the complaint. Complainants rely on investments with

¹¹⁸ There is evidence that there were separate concurrent projects in this timeframe related to wrist-based pulse oximetry at Masimo and Cercacor. *See* Tr. (Kiani) at 119:4-8 (describing a "friendly rivalry" with Cercacor in 2018). It is unclear whether some of these projects were related to product designs that are distinct from the asserted "Masimo Watch" prototypes.

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respect to the development of "Masimo Watch" prototypes to show that a domestic industry existed at the time of the complaint. CIB at 288-309. Complainants rely on Masimo financial information that was presented in appendices to the complaint that were extracted from Masimo's records. Tr. (Young) at 485:10-488:17; CDX-0006C.002 (citing CX-0629C; CX-0635C; CX-0624C; CX-0623C; CX-0646C; CX-0632C; CX-0628C; CX-0638C); CDX-0006C.003 (citing CX-0641C; CX-0645C; CX-0644C; CX-0640C; CX-0648C; CX-0649C; CX-0642C). Complainants have separately identified investments with respect to plant and equipment and labor and capital. *See* CIB at 301-09.

1. Plant and Equipment Expenditures

Mr. Kiani described research and development on wrist-based pulse oximetry at Masimo and Cercacor in Irvine, California. Tr. (Kiani) at 119:9-12. Mr. Young, Masimo's CFO and Executive Vice President, presented certain facility expenditures between the third quarter of 2019 and the first quarter of 2021 at Masimo's Irvine headquarters and a nearby manufacturing facility. Tr. (Young) at 481:17-20, 488:18-490:16; CDX-0006C.004. Complainants do not rely on the amounts reported by Mr. Young, however, instead identifying adjusted (and lower) amounts for plant and equipment investment that were calculated by its expert, Mr. McGavock. CIB at 301-02; *see* Tr. (McGavock) at 539:16-23; CDX-0015C.006. For the 2018-2021 timeframe, Masimo identifies in plant and equipment expenditures for Masimo Watch research and development at Masimo's headquarters (52 Discovery), and in plant and equipment expenditures for manufacturing at the Laguna Canyon Road facility. CIB at 301-02

Mr. McGavock testified that he "followed basically the same methodology as Mr. Young did." Tr. (McGavock) at 538:4-15. Mr. Young explained that he allocated the operating expenses at Masimo headquarters using the portion of square footage of the facility that was

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dedicated to R&D and then the percentage of employee time that was spent on the Masimo Watch. Tr. (Young) at 489:22-16. With respect to the Laguna Canyon Road facility, Mr. Young allocated operating expenses based on an estimate that "about percent of the square footage of that facility is dedicated to the Masimo Watch project." *Id.* at 489:10-16. Mr. Young explained that Masimo's operating expenses include "maintenance and utilities, property taxes, and other facility-related costs." *Id.* at 489:17-21.

Apple contends that Mr. McGavock's analysis was unreliable, arguing that it was based on Masimo financial data that has not been verified and estimates from Masimo employees without sufficient explanation. RIB at 245-48; RRB at 152-54. With respect to the allocation of Masimo's facility operating expenses, Apple argues that there is no documentary evidence to support the square footage allocations, such as floor plans. RRB at 157. Apple further identifies evidence that the portion of the Laguna Canyon Road facility designated for Masimo Watch manufacturing is shared by other projects. RIB at 251 (citing CX-0629C). A Masimo witness admitted that the allocation percentage was based on projections, without confirming that the space was used for the Masimo Watch. RX-1202C (Kaufman Dep. Tr.) at 71:12-19. With respect to allocations of employee time, Apple argues that there is no documentary evidence in the record, such as time sheets or calendar entries, to support these estimates, and the Masimo witness testimony is insufficient to explain the basis for the allocations. CRB at 152-54.

In consideration of the parties' arguments, the undersigned finds that Complainants have provided a sufficiently reliable allocation of 2018-2021 facility operating expenses for research and development at Masimo's headquarters for the Masimo Watch. The time allocations relied upon by Mr. McGavock appear to be reasonable, and the Commission has relied on similar allocations of square footage and employee time based on witness testimony. *See Certain Solid*

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State Storage Drives, Stacked Electronics Components, and Products Containing Same, Inv. No. 337-TA-1097, Comm'n Op. at 17-20, EDIS Doc. ID 649139 (June 29, 2018) (relying on a manager's estimates for allocations of square footage and employee time); see also Certain Electrical Connectors and Cages, Components, And Products Containing the Same Thereof, Inv. No. 337-TA-1241, Final ID at 362-66, EDIS Doc. ID 767918 (Mar. 11, 2022) (finding "good faith" estimates of employee time to be reliable), not reviewed in relevant part by Comm'n Notice, EDIS Doc. ID 779717 (Sept. 8, 2022). Mr. Young explained that the time allocations were prepared with Masimo's "executive team members as well as leaders of different functions and departments across the organization." Tr. (Young) at 486:16-18; see Tr. (Scruggs) at 436:8-12 (estimated of square footage); Tr. (Al-Ali) at 322:6-14 (estimated headcounts and percentages of time for Masimo Watch engineers); Tr. (Muhsin) at 359:12-360:5 (estimated time for executives). The allocation of manufacturing expenses at the Laguna Canyon Road facility does not appear to be reliable, however, because it is based on a projection without confirmation that any of the Masimo Watch prototypes were manufactured there. See RX-1202C (Kaufman Dep. Tr.) at 71:12-72:15 (explaining that the percent allocation was based on a projection of the square footage that would be used for Masimo Watch manufacturing). Complainants cite testimony from the hearing that Masimo Watch prototypes were manufactured at Masimo's California facilities, see CRB at 175, but there is no evidence specifically placing any manufacturing at the Laguna Canyon Road facility. These manufacturing-related expenditures cannot be considered part of the alleged domestic industry without evidence that operations in the Laguna Canyon Road facility were "with respect to" the domestic industry articles.

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Accordingly, the qualifying plant and equipment expenditures for the Masimo Watch are limited to the in operating expenses at Masimo's headquarters for Masimo Watch research and development from 2018-2021. 119

2. Labor and Capital Expenditures

Complainants further rely on Masimo's employment of labor and capital with respect to the Masimo Watch. CIB at 303-05. Using a timeframe from the third quarter of 2019 to the first quarter of 2021, Mr. Young identified several categories of Masimo's labor and capital expenditures with respect to the Masimo Watch. Tr. (Young) at 488:18-496:19; CDX-0006.004. Using the projections and allocation methods described above, Mr. Young calculated in operating expenditures for the Laguna Canyon Road manufacturing facility for the Masimo Watch at. Tr. (Young) at 489:2-21; CDX-0006C.005. Relying on estimates of square footage and employee time, Mr. Young calculated in operating expenditures for research and development at Masimo's headquarters. Tr. (Young) at 489:22-490:15; CDX-0006C.004-.008; CX-0635C. Mr. Young calculated in capital items expenditures related to the Masimo Watch, based on purchases of "new machinery that we used in production of the watch, as well as existing machinery that was repurchased." Tr. (Young) at 490:19-492:10; CDX-0006C.009-.010; CX-0635C; CX-0611C; CX-0835C. He also identified equipment supplies for the Masimo Watch. Tr. (Young) at 492:11-15; CDX-0006C.011. in labor expenditures for research and development related to Mr. Young calculated the Masimo Watch, explaining that this amount was determined by using estimated time

¹¹⁹ As discussed above, the most relevant timeframe for domestic industry expenditures is the period when the Masimo Watch prototypes were built between 2019 and 2021. Expenditures extending to 2018 may be less relevant, but the inclusion of this additional year in Masimo's plant and equipment investments does not affect the domestic industry analysis because, as discussed *infra*, Complainants have not identified any context for assessing the significance of these investments.

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allocations for Masimo employees. Tr. (Young) at 492:20-493:7; CDX-0006C.012-.013; CX-0635C. He also identified in labor expenditures for executives who worked on Masimo Watch. Tr. (Young) at 493:8-494:17; CDX-0006C.014-.015; CX-0624C. Mr. Young further identified for clinical labor, for regulatory and quality assurance, and for recruiting labor for the Masimo Watch project. Tr. (Young) at 494:21-495:7; CDX-0006C.016-.018. Mr. Young calculated in expenditures for external watch design, which were paid by Masimo to third parties Tr. (Young) at 495:8-496:19; CX-0617C; CX-0620C.

Complainants also identify an estimated in investments in research and development for wrist-worn technology dating back to 2001, which was calculated by taking Masimo's total R&D investments in the United States and allocating the time of Masimo employees that was related to wrist-worn technology. CIB at 305; Tr. (Young) at 497:1-20.

Apple argues that Mr. Young's estimates are unreliable, contending that the amounts are based on Masimo financial data that has not been verified and estimates from Masimo employees without sufficient explanation. RIB at 245-48. Apple argues that there is no documentary evidence in the record, such as time sheets or calendar entries, to support Complainants' estimates of employee time, and that Masimo's witness testimony is insufficient to explain the basis for these allocations. CRB at 152-54. Apple further argues that Complainants improperly rely on expenditures related to early development of products that are not asserted to practice any claim of the Poeze patents or the '745 patent. RIB at 249-50; RRB at 155. With respect to the alleged manufacturing expenditures, Apple argues that the square footage allocation is unreliable and there is no evidence that prototypes were manufactured at that facility. RIB at 250-51; RRB at 156. With respect to Masimo's R&D expenditures, Apple argues that there is insufficient

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evidence in the record describing the activities of Masimo employees or the use of Masimo facilities. RIB at 252-53, 271; RRB at 157. Apple argues that the alleged watch equipment supplies are not cognizable expenditures because there is no evidence in the record identifying the purchased supplies. RIB at 267. Apple contends that no consistent methodology was used to estimate the amount of executive labor, and it is not clear whether this includes non-cognizable expenditures, such as administrative overhead. *Id.* at 269-70. Apple further argues that there is insufficient evidence to substantiate Masimo's third-party payments for watch design or regulatory expenses. *Id.* at 271-72. Apple also argues that the estimate for recruiting labor expense is unreliable. *Id.* at 272.

In consideration of the parties' arguments, the undersigned finds that a majority of Complainants' asserted labor and capital expenditures have been reliably quantified for consideration as part of the alleged domestic industry in this investigation. As discussed above in the context of the plant and equipment expenditures, the time allocations for Masimo's employees are supported by the testimony of Masimo witnesses, which is similar to evidence that has been relied upon in other investigations. *See* Tr. (Young) at 492:20-493:7 ("We worked with our leaders of engineering, and they put together a listing of all the employees working on the watch. I think there's over employees on the spreadsheet. They also provided the time allocation by month . . . And then we applied that to the compensation by each of those employees to come up with the allocation of R&D dollars."). Complainants have identified the names and salaries of each employee involved in the Masimo Watch project with monthly estimates of their time from 2019 to 2021. CX-0635C. Complainants provide a similar

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accounting for executive labor. CX-0624C. 120 Complainants further identify expenditures for recruiting engineers to work on the Masimo Watch. Tr. (Young) at 494:21-495:7; CDX-0006C.016-.018. Apple argues that Complainants have provided insufficient detail regarding the staffing of particular Masimo Watch projects or the specific activities of Masimo executives and employees, RIB at 269-71, but Mr. Young explained that such detailed information is not tracked in Masimo's financial records. Tr. (Young) at 484:22-25. As discussed above, Masimo engineers explained that the asserted Masimo Watch prototypes were "iterations" of a product design that was continuously developed in the years leading up to the filing of the complaint. See Tr. (Muhsin) at 342:25-343:7, 345:2-7; Tr. (Scruggs) at 393:12-20, 394:12-18, 395:7-15, 396:2-13, 397:7-24, 398:1-23, 402:2-12. Mr. Young further explained that with respect to the time allocations, he and other Masimo executives "were trying to also be conservative." Tr. (Young) at 493:14-494:6. With respect to Masimo's recruiting expenditures, the relevant human resources staff are identified in a spreadsheet, CX-0632C, and the allocations of time are supported by estimates made by Masimo employees. See RX-1202C (Kaufman Dep. Tr.) at 18:17-188:12. The Commission has held that with respect to domestic industry, "[a] precise accounting is not necessary, as most people do not document their daily affairs in contemplation of possible litigation." Stringed Musical Instruments, Inv. No. 337-TA-586, Comm'n Op., 2009 WL 5134139, at *17 (December 2009); see also Certain Electronic Devices, Inv. No. 337-TA-701, Order No. 58 at 5, EDIS Doc. ID 439031 (Nov. 18, 2010) ("[T]he Administrative Law

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¹²⁰ Apple argues that the executive labor should be excluded because it may include "administrative overhead," RIB at 269-70, but the Commission's exclusion of "administrative overhead" concerns those activities "associated with importation of the domestic industry products." *Certain Bone Cements*, Inv. No. 337-TA-1153, Comm'n Op. at 22, EDIS Doc. ID 731649 (Jan. 25, 2021). Apple has not persuasively argued that administrative expenditures should be excluded for executives who are managing employees working on research and development in the United States.

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Judge declines as a matter of law to give credence to Apple's pro forma objections that Nokia has failed to give a precise accounting or failed to provide underlying documentation for sworn witness testimony."), not reviewed by Comm'n Notice, EDIS Doc. ID 440675 (Dec. 20, 2010). The allocations for employee and executive labor expenditures are thus reasonable, and these expenditures account for a majority of the asserted labor and capital, with for employees engaged in Masimo Watch research and development, for executives involved with the Masimo Watch project, and in expenditures for recruiting. See CDX-0006C.012-.015, .016-.018.

With respect to the expenditures paid to outside firms for the design of the Masimo Watch, Apple argues that some of these may be foreign expenditures. RIB at 271-72. See Certain Products Having Laminated Packaging, Laminated Packaging, and Components Thereof, Inv. No. 337-TA-874, Comm'n Op. at 17, EDIS Doc. ID 517360 (Sept. 3, 2013) (finding that payments to vendors cannot be counted as part of the domestic industry where complainant "did not show that the . . . vendors manufacture the laminated packages in the United States"). Complainants submit that Masimo contracted with U.S.-based entities for these services, CRB at 176, but it is unclear whether the work will be conducted in the United States. identifies a U.S. address, but with additional addresses in The presentation from Germany and China. CX-0620C at 23. The contract with identifies a U.S. address. but the evidence is insufficient to show activities taking place in the United States before the time of the complaint. See CX-0617C (identifying CX-0618C (describing design milestones extending to the end of 2021). 121 Based on this record, the

¹²¹ Apple contends that . RIB at 271.

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undersigned agrees with Apple that these expenditures should not be counted as part of the alleged domestic industry. In any case, these expenditures are relatively small in comparison to Masimo's R&D expenditures, see CIB at 304-05, and whether these additional expenditures are counted as part of the domestic industry has no impact on the determination with respect to significance, infra, which is based on the number of Masimo employees engaged in R&D for the Masimo Watch in the United States.

Certain of Complainants' other claimed expenditures are also insufficiently supported by evidence in the record, and whether these additional expenditures are counted as part of the domestic industry has no impact on the determination with respect to significance, *infra*, which is based on Masimo's research and development activities. As discussed above in the context of plant and equipment, the operating expenses related to manufacturing are not supported by a reliable allocation or any evidence that the domestic industry articles were manufactured at the Laguna Canyon Road facility. In addition, Complainants have not identified evidence in the record cataloguing the capital items or the supplies that correspond to the asserted expenditures—Mr. Young's testimony only identifies one piece of machinery with a "picture of the piece of equipment being used in the production of the watch," Tr. (Young) at 491:14-23 (citing CX-0611C), but even for this piece of equipment, Complainants do not explain what it does or how it is related to any Masimo Watch prototypes. The claimed labor expenses related to clinical studies and regulatory and quality assurance appear to relate to the work of a small number of Masimo employees, but Complainants do not identify the employees or explain what they do. See CX-0623C; CX-0646C.

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3. Significance of Investments

As discussed above, Complainants have identified approximately in qualifying plant and equipment expenditures based on operating expenses at Masimo's headquarters, and approximately in qualifying labor expenditures for employees, executives, and recruiting—each of these amounts relates to research and development of Masimo Watch prototype products. 122

Complainants argue that Masimo's domestic investments are significant because 100% of the research and development activities for the Masimo Watch occur in the United States. CIB at 307; see Tr. (Kiani) at 321:23-322:5. Mr. McGavock testified that it was his understanding that the Masimo Watch was Masimo's

Tr. (McGavock) at 543:1-544:14. Mr. Kiani described the Masimo Watch as

Tr. (Kiani) at 126:19-23.

With respect to the labor expenditures, Complainants submit that the headcount of employees (full-time equivalent) in the first quarter of 2021 is significant. CIB at 307; see Tr. (Young) at 504:9-13; CX-0648C. Complainants submit that percent of Masimo's R&D engineers were working on the Masimo Watch at that time. CIB at 308; see Tr. (McGavock) at 544:21-545:25; CDX-0015C.012. Por the Masimo engineers working on the Masimo Watch,

Approximately in operating expenses is also asserted as a capital expenditure, representing the same expenditures recognized as investments in plant and equipment. Regardless of whether this amount is added to the labor expenditures under subparagraph (B), it would not affect the significance analysis below.

¹²³ There is a discrepancy between Mr. McGavock's testimony and his demonstrative regarding the "percent" figure. He said: "The portion of the Masimo's R&D engineering time dedicated to the watch was percent at the first quarter of 2021." Tr. (McGavock) at 545:12-14. His demonstrative reads: "Portion of Masimo R&D engineers dedicated to the Watch: at Q1 2021." CDX-0015C.012. Apple does not appear to dispute that the refers to a percentage of Masimo R&D engineer headcount, as described in the demonstrative. See RIB at 274.

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of their time was spent on the Masimo Watch. CIB at 308; see Tr. (McGavock) at 544:21-545:25; CDX-0015C.012. Mr. Al-Ali identified a specific team of engineers that

for the Masimo Watch. Tr. (Al-Ali) at 323:18342:21; see also Tr. (Muhsin) at 34:14-345:1. Mr. McGavock identified , and
Complainants argue that their work was significant. CIB at 308; Tr. (McGavock) at 544:21545:25; CDX-0015C.012. Complainants argue that Masimo's investments are significant in absolute terms. CIB at 308-09.

Apple argues that Complainants have failed to demonstrate the significance of the claimed expenditures. RIB at 253-56, 272-74. With respect to plant and equipment, Apple argues that the facility operating expenditures related to research and development for the Masimo Watch only represent about of Masimo's total facility operating expenditures. RIB at 255. Apple submits that Masimo's R&D investments with respect to the Masimo Watch represent only of Masimo's overall R&D investments. RIB at 273; Tr. (Thomas) at 1305:2-9. Apple argues that there is no significance to Complainants' claim that the Masimo Watch represents Masimo's because Masimo has historically focused on clinical products. RIB at 254-55 (citing Tr. (Kiani) at 140:8-11). Apple argues that Complainants' reliance on allocation percentages to represent significance is unsupported and unreliable. RIB at 274; see Tr. (Thomas) at 1306:7-13 ("[U]sing percentages to arrive at a number and then circularly using those percentages to represent significance, I think, is misleading and inappropriate."). Apple argues that the employment of does not demonstrate significance, and there is no evidence for what those engineers are doing after completion of the . RIB at 274; Tr. (Thomas) at 1306:14-18.

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In consideration of the parties' arguments, the undersigned finds that Complainants have shown significant employment of labor with respect to Masimo's investments in research and development for the Masimo Watch. The in labor expenditures is quantitatively significant in the context of Masimo's broader research and development efforts, because it employees (full-time equivalent) representing over percent of Masimo's research and development engineers. See Tr. (Young) at 504:9-13; Tr. (McGavock) at 545:12-14; CDX-0015C.012. Apple questions the reliability of Masimo's allocations of employee time, RIB at 274, but as discussed above, the allocations are supported by reliable witness testimony. See Tr. (Young) at 492:20-493:7. Apple argues that the investments in the Masimo Watch are a small fraction of Masimo's overall research and development budget, RIB at 273, but the fact that Masimo invests in other products does not diminish the significance of Masimo's investments in the Masimo Watch, because "[s]ignificance is based on the marketplace conditions regarding the articles protected by the Asserted Patents," and activities regarding "other products is not pertinent to this analysis." Certain Carburetors and Products Containing Such Carburetors, Inv. No. 337-TA-1123, Comm'n Op. at 28, EDIS Doc. ID 692517 (Oct. 28, 2019). The significance of Masimo's investments in the Masimo Watch is corroborated by qualitative evidence that this was Masimo's See Tr. (Kiani) at 12:19-2; Tr. (McGavock) at 543:1-544:14. In addition, Masimo's investments are significant

12:19-2; Tr. (McGavock) at 543:1-544:14. In addition, Masimo's investments are significant because all of the research and development for the Masimo Watch has occurred in the United States. CIB at 307; see Tr. (Kiani) at 321:23-322:5; see Gas Spring Nailer Prods. and Components Thereof, Inv. No. 337-TA-1082, Comm'n Op. at 83, EDIS Doc. ID 709073 (Apr. 28, 2020) (finding quantitative significance where "all, i.e., 100 percent, of Kyocera's R&D and

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engineering expenditures relating to complainant's [DI products] occurs in the United States."), vacated and remanded on other grounds, 22 F.4th 1369 (Fed. Cir. 2022); Certain Shingled Solar Modules, Components Thereof, and Methods for Manufacturing the Same, Inv. No. 337-TA-1223, Initial Determination at 60, EDIS Doc. ID 756910 (Oct. 22, 2021) (finding quantitative significance where 100% of research and development activities were based in the United States), not reviewed in relevant party by Comm'n Notice, EDIS Doc. ID 762554 (Feb. 4, 2022).

Complainants also submit that Masimo's investments in research and development for the Masimo Watch are qualitatively significant, because it represents

CIB at 307; Tr. (Kiani) at 121:11-123:16, 126:19-23; Tr. (McGavock) at 543:16-544:14. Complainants also point to the "custom designing and building tools and equipment" for the Masimo Watch. CIB at 307; Tr. (Scruggs) at 433:13-15; Tr. (McGavock) at 543:1-544:14. In particular, Complainants cite the design of a CIB at 307-08; Tr. (Al-Ali_ at 323:18-324:25; Tr. (Muhsin) at 344:14-345:1. These qualitative factors demonstrate the importance of the Masimo Watch development to Masimo, and this supports the finding of quantitative significance.

Complainants have not, however, persuasively shown that Masimo's investments and plant and equipment are quantitatively significant. The floor space in Masimo's headquarters that is attributable to work on the Masimo Watch only represents about of the facility. *See* RIB at 255; Tr. (Young) at 489:22-490:13 (allocating percent of the floor space to R&D and between percent of R&D to the Masimo Watch); CX-0635C. In their briefing, Complainants have not placed their plant and equipment expenditures in any appropriate context that shows significance. *See Certain Earpiece Devices and Components Thereof*, Inv. No. 337-

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TA-1121, Comm'n Op. at 19, EDIS Doc. ID 693820 (Nov. 8, 2019) (remanding a summary determination on the economic prong because complainant did "not provide context of the company's operations, the marketplace, or the industry in question necessary to understand whether the relative value of its domestic activities and investments is significant or substantial."). ¹²⁴

* * *

Accordingly, Complainants have met the economic prong of the domestic industry requirement based on the existence of a domestic industry at the time of the complaint with respect to significant investments in labor and capital for the research and development of the Masimo Watch. Complainants have thus satisfied the domestic industry requirement with respect to the Poeze patents and the '745 patent.

D. Domestic Industry in the Process of Being Established

Complainants further argue that there is a domestic industry in the process of being established based on Masimo's projected expenditures for the Masimo Watch. CIB at 305-09.

Mr. Young explained that at the time of the complaint, Masimo's financial department worked with engineering leaders and other Masimo employees to create a forecast of expected expenditures from the second quarter of 2021 to 2023. Tr. (Young) at 500:23-503:3; CDX-

¹²⁴ Complainants' other arguments for significance fail for the same reasons. It is unclear why the fact that engineers working on the Masimo Watch spend of their time on the Masimo Watch should be evidence for significance. See CIB at 308; RIB at 274. There is evidence that the design of a was qualitatively important to Masimo, but Complainants fail to explain why the work of these engineers is quantitatively significant. See CIB at 308; RIB at 274.

¹²⁵ Masimo also relies on post-complaint evidence for the number of employees it has hired, a 2022 corporate acquisition, and a statement in Masimo's 2021 Earnings Presentation, CIB at 307-09, but this evidence will not be considered in the context of the economic prong, as discussed *supra*. Whether Complainants have shown a domestic industry in the process of being established will be determined based on the projections made by Masimo before the filing of the complaint.

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development on the Masimo Watch during this timeframe. Tr. (Young) at 502:7-18; CDX-000C.032. Masimo also projected production costs for the Masimo Watch, estimating that there would be between and in US-based production costs in 2022 and between and in US-based production costs in 2023. Tr. (Young) at 502:19-503:3; CDX-000C.033. Mr. McGavock relied on these projections to estimate that of the cost of goods for the Masimo Watch would be incurred in the United States. Tr. (McGavock) at 545:8-9; CDX-0015C.012. Complainants further argue that Masimo's growing number of Masimo Watch personnel and the expansion of the Laguna Canyon Road manufacturing facility shows that a domestic industry is in the process of being established. CRB at 176-77; see Tr. (McGavock) at 542:14-20, 563:8-13, 574:25-575:2.

Apple argues that Complainants have produced no definitive timeline for the completion of the Masimo Watch, citing the absence of business plans or other documentation in the evidentiary record. RIB at 258-60, 275; RRB at 158-59, 172. Apple further argues that Masimo's projected expenditures are unsupported and unreliable. RIB at 258-60; RRB at 151, 156, 169-70. Apple argues that Complainants' projections for the share of domestic expenditures in the manufacturing of future Masimo Watch products is unreliable and notes that the for later versions of the Masimo Watch. CIB at 273 (citing CX-0629C). Apple suggests that Masimo Watch manufacturing would likely be

Apple argues that Masimo's projections for Masimo Watch manufacturing was , RIB at 258-60, RRB at 169-70, but this post-complaint evidence will not be considered in the context of the economic prong analysis.

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. *Id.* at 273-74; *see* RX-1211C (Young Dep. Tr.) at 84:14-17; Tr. (McGavock) at 570:7-10.

In consideration of the parties' arguments, the undersigned finds that Complainants have satisfied the economic prong of the domestic industry requirement with respect to a domestic industry in the process of being established for the Masimo Watch. The Commission has held that a domestic industry is in the process of being established when (1) a complainant takes "the necessary tangible steps to establish such an industry in the United States," and (2) there is a "significant likelihood that the industry requirement will be satisfied in the future." *Certain Stringed Musical Instruments & Components Thereof*, Inv. No. 337-TA-586, Comm'n Op. at 16-17, EDIS Doc. ID 300615 (May 16, 2008). For the reasons discussed below, the evidentiary record shows that Masimo has met both requirements based on evidence of activities and investments before the filing of the complaint and projections that were made at the time of the filing of the complaint.

Masimo's design and production of Masimo Watch prototypes represent tangible steps toward the establishment of a domestic industry with respect to the Masimo Watch. As explained by Mr. Scruggs, these prototypes were designed and built from 2019 through 2021, incorporating features asserted in the claims of the Poeze patents and the '745 patent. *See* Tr. (Scruggs) at 394:12-18, 395:7-15, 396:2-13, 397:7-24, 398:1-23. Mr. Kiani explained that these prototypes were part of the ongoing project to design and manufacture the Masimo Watch. Tr. (Kiani) at 121:7-122:8, 123:17-124:4; CX-0364C; CX-0783C. As discussed above in the context of Masimo's pre-complaint investments in labor, the research and development of the Masimo Watch prototypes involved up to Masimo employees (working the equivalent of full-time employees). *See* Tr. (Young) at 504:9-13. There is further evidence that at the time of the filing

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of the complaint, Masimo planned to hire additional engineers to work on the Masimo Watch project, *see* Tr. (Young) at 502:7-18, CDX-000C.032, and in preparation for this expanding workforce, Masimo had taken the tangible step of hiring additional recruiting staff. *See* Tr. (Young) at 495:3-7; RX-1202C (Kaufman Dep. Tr.) at 18:17-188:12; CX-0632C. Masimo has also contracted with external design firms for work on future Masimo Watch products. *See* Tr. (Young) at 495:16-496:19; CX-0617C; CX-0618C; CX-0620C. The record thus shows that Masimo was taking tangible steps towards the design and manufacture of the Masimo Watch at the time of the complaint.

As discussed above, Masimo invested in labor expenditures in the years leading up to the complaint for research and development with respect to Masimo Watch prototypes, and this amount is both quantitatively and qualitatively significant in the context of Masimo's research and development activities. The record further shows that Masimo projected increased hiring for the Masimo Watch, and this further employment of labor would be significant for the same reasons as Masimo's past employment of labor. *See* Tr. (Young) at 494:21-495:7; CDX-0006C.016-.018. Accordingly, there is a significant likelihood that the economic prong of the domestic industry requirement will be satisfied in the future with respect to the Masimo Watch based on Masimo's past and future investments in labor for research and development.

In addition, Masimo's projected expenditures for manufacturing of the Masimo Watch are further evidence for a significant likelihood that the domestic industry requirement will be satisfied in the future. Masimo has projected that about percent of its Laguna Canyon Road

¹²⁷ Even if this work is not conducted in the United States, *see* RIB at 271-72, the engagement of these design firms is evidence of Masimo's plans for the Masimo Watch.

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facility will be used for manufacturing the Masimo Watch. Tr. (Young) at 49:10-16; RX-1202C (Kaufman Dep. Tr.) at 71:12-72:15. Masimo has also projected that of the manufacturing Masimo Watch in 2021 would be domestic. Tr. (McGavock) at 545:8-9; CDX-000C.033; CX-0629C. The domestic share of manufacturing costs was projected to Masimo Watch in 2022 and to for a Masimo Watch in 2023. See RIB at 273; CX-0629C. Apple has identified reasons to be skeptical of the high projection for Masimo Watch, see RIB at 273-74, Tr. (Thomas) at 1305:10-19, but even the figure would likely support a finding that the domestic industry requirement has been satisfied. Cf. Certain Self-Anchoring Beverage Containers, Inv. No. 337-TA-1092, Comm'n Op. at 13, EDIS Doc. ID 683010 (Jul. 4, 2019) (finding domestic investments representing 9 percent of the sales revenue for the domestic industry product to be significant). Moreover, even if Masimo's domestic contribution to manufacturing the Masimo Watch dropped in the future, the domestic industry requirement could still be satisfied based on Masimo's significant investments in research and development, as long as Masimo was continuing to make appropriate qualifying domestic investments. See Certain Television Sets, Television Receivers, Television Tuners, and Components Thereof, Inv. No. 337-TA-910, Comm'n Op. at 68, 2015 WL 6755093, at *36 (Oct. 30, 2015) ("Past expenditures may be considered to support a domestic industry claim so long as those investments pertain to the complainant's industry with respect to the articles protected by the asserted IP rights and the complainant is continuing to make qualifying investments at the time the complaint is filed."); Hyosung TNS Inc. v. Int'l Trade Comm'n, 926 F.3d 1353, 1362 (Fed. Cir. 2019) (affirming Commission's "conclusion that a past investment may, by virtue of its connection to ongoing field service and assembly expenses, support a finding that the economic prong of the domestic industry requirement is met."). Although the level of

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investment can be disputed, the record unequivocally shows that Masimo expected to continue investing in the Masimo Watch in the United States with expenditures in research and development and manufacturing. *See* Tr. (Kiani) at 123:17-124:22 (describing 2020 presentation for Masimo Watch, CX-0783C); Tr. (Young) at 500:23-503:3 (describing projections for 2021-2023 spending).

* * *

Accordingly, Complainants have identified investments and projections for investments at the time of the complaint showing, by a preponderance of the evidence, a domestic industry in the process of being established with respect to the Masimo Watch. As discussed above, Complainants have also shown that Masimo Watch products meeting the limitations of certain claims of the Poeze patents and the '745 patent were in the process of being developed at the time of the complaint. Complainants have thus satisfied the economic prong of the domestic industry requirement for the Poeze patents and the '745 patent based on an industry in the process of being established.

VIII. DOMESTIC INDUSTRY – ECONOMIC PRONG ('127 PATENT)

For the '127 patent, Complainants rely on investments with respect to research and development and manufacturing of Masimo's rainbow® sensors to satisfy the economic prong of the domestic industry requirement. *Id.* at 302-03, 309-10.

A. Domestic Industry Existing at the Time of the Complaint

As discussed above in the context of the technical prong, the domestic industry products include "early" rainbow® sensors sold before 2009, which have been shown to practice claim 9 of the '127 patent, and "current" rainbow® sensors sold after 2009, which have not been shown

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to practice claim 9 of the '127 patent. ^{128,129} Complainants have not allocated their domestic industry expenditures between early and current rainbow® sensors, however, and this precludes any reliable domestic industry analysis. *See Certain Subsea Telecomm. Sys. and Components Thereof*, Inv. No. 337-TA-1098, Comm'n Op. at 41, EDIS Doc. ID 691678 (Oct. 21, 2019) ("The Commission has found that complainants have not satisfied the domestic industry requirement where the complainant failed to allocate expenses to account for non-domestic industry products that do not practice the patent.").

Even if Complainants had allocated their domestic industry expenditures between the early and current rainbow® sensors, Complainants cannot satisfy the domestic industry requirement based only on investments in the early rainbow® sensors, because the record indicates that these products were discontinued in favor of the current rainbow® sensors in 2009, more than a decade before the complaint in this investigation was filed. See CRB at 10; Tr. (Diab) at 233:16-20. In such circumstances, the Commission has required a showing of "ongoing qualifying activities under section 337(a)(3) at the time the complaint is filed." See Certain Television Sets, Television Receivers, Television Tuners, and Components Thereof, Inv. No. 337-TA-910, Comm'n Op. at 68, 2015 WL 6755093, at *37 (Oct. 30, 2015); see also

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¹²⁸ The parties dispute whether Complainants have sufficiently identified which products comprise the asserted Masimo rainbow® sensors. CIB at 36; RIB at 261; RRB at 160. As discussed above in the context of the technical prong, the undersigned finds that Complainants have sufficiently identified the asserted rainbow® sensors on a sales spreadsheet. CX-0649C.

Apple argues that there are at least two models of rainbow® sensors that have not been asserted to practice the '127 patent, RRB at 160, but Complainants have acknowledged that the rainbow® sensors relevant to this investigation exclude these two models. *See* CIB at 36 n.4 (citing Tr. (Diab) at 210:13-19 ("All of rainbow sensors use wavelength correction except for a couple of them. One is an acoustic sensor, and the other one, it's called Light Set 1, but the rest of them all use temperature correction.")). There is no indication that those two models are listed in the financial spreadsheet exhibit that lists the asserted rainbow® sensors. *See* CX-0649C.

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Certain Marine Sonar Imaging Devices, Including Downscan & Sidescan Devices, Prod.

Containing the Same, & Components Thereof, Inv. No. 337-TA-921, Comm'n Op. at 55-57,

EDIS Doc. ID 571940 (Jan. 6, 2016) ("The Commission, thus, has found, in various investigations, a domestic industry based on a complainant's past activities relating to a discontinued product where the complainant has shown continuing qualifying investments.").

There is no evidence in the record showing that Masimo has continued to invest in the early rainbow® sensors after their discontinuation. Complainants have not identified any continuing investments in warranty, customer service, or maintenance of early rainbow® sensors—the asserted domestic industry expenditures are related to research and development and manufacturing—these activities appear to have been directed to the current rainbow® sensors since 2009. CIB at 302-03, 309-10.

Accordingly, based on the present record, Complainants have failed to show that a domestic industry existed at the time of the complaint with respect to the early rainbow® sensors that have been shown to practice claim 9 of the '127 patent.

B. Domestic Industry in the Process of Being Established

Complainants also assert that there is a domestic industry in the process of being established for the rainbow® sensors, relying on projections of expenditures after the time the complaint was filed. CIB at 288, 299. These projected expenditures relate to research and development and manufacturing, CIB at 302-03, 309-10, and as discussed above, such expenditures appear to relate only to the current rainbow® sensors after 2009. Complainants have not attempted to explain how a domestic industry could be in the process of being established with respect to discontinued products. On this record, Complainants have failed to

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show that a domestic industry was in the process of being established with respect to the early rainbow® sensors.

C. Asserted Domestic Industry Expenditures

As discussed above, Complainants have improperly aggregated their domestic industry expenditures for the early rainbow® sensors and the current rainbow® sensors, and there is insufficient evidence in the record to satisfy the economic prong of the domestic industry requirement with respect to the early rainbow® sensors alone. In the event the current rainbow® sensors were found to practice the '127 patent as well, however, the undersigned addresses certain of Complainants' domestic industry expenditures below to determine whether the asserted domestic industry expenditures are significant pursuant to subparagraphs (A) and (B) of section 337(a)(3). 19 U.S.C. § 1337(a)(3).

1. Plant and Equipment

Complainants identify Cercacor, which is headquartered in Irvine, California, as the developer of Masimo's rainbow® technology. CIB at 299 (citing Tr. (Kiani) at 94:8-17, 119:9-12). Complainants further submit that Masimo manufactures the LEDs for the rainbow® sensors in a facility in Hudson, New Hampshire. CIB at 299; CX-0636C. Using allocations of square footage and employee time, Mr. McGavock calculated that Masimo invested in facility operating expenses at Masimo's headquarters for research and development of the rainbow® sensors between 2018 and the first quarter of 2021. Tr. (McGavock) at 547:6-13; CDX-0015C.014; see CIB at 302-03. He estimated in allocated research and development expenditures before 2018 at that facility and added an additional in

¹³⁰ Cercacor (formerly known as Masimo Laboratories) is a spinoff from Masimo that collaborates with Masimo on R&D for nonvital parameter monitoring. *See* Tr. (Kiani) at 93:12-94:7; *see also* CX-1612C.

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allocated research and development expenditures at an older Masimo facility. *Id.* He calculated in operating expenditures for manufacturing rainbow® sensors at Masimo's Laguna Canyon Road facility between 2018 and the first quarter of 2021, and an additional in expenditures before 2018. *Id.* He further calculated in operating expenditures for manufacturing LEDs for rainbow® sensors at Masimo's New Hampshire facility between 2018 and the first quarter of 2021, and an additional in expenditures before 2018. *Id.* As a measure of significance, Complainants submit that "for of Masimo's facility investments for rainbow® are in the U.S." CIB at 310; Tr. (McGavock) at 549:8-14; CDX-0015C.017.

Apple contends that Mr. McGavock's analysis was unreliable, arguing that it was based on Masimo financial data that has not been verified with allocations that have not been explained. RIB at 262-64; RRB at 160-62. Apple argues that Complainants have failed to offer any documents or testimony explaining how employee time was estimated for rainbow® sensor R&D. RIB at 263; RRB at 161. With respect to manufacturing expenses, Apple argues that there is no explanation for how Complainants calculated the "standard cost" for the rainbow® sensor products. RIB at 263-64; RRB at 162. Apple argues that Complainants have failed to offer any evidence that explains how the LED manufacturing in New Hampshire relates to the rainbow® sensors and questions the accuracy of certain calculations of expenditures. RIB at 264; RRB at 162. Apple further argues that Mr. McGavock's claim that Masimo's facility expenses are domestic is not explained in the record, and it is contradicted by evidence that Masimo has significant manufacturing facilities in Mexico. RIB at 264-65; RRB at 163.

In consideration of the parties' arguments, the undersigned finds that Complainants' asserted expenditures are sufficiently reliable for the domestic industry analysis. With respect to these expenditures, Mr. McGavock explained that he "used the same methodology applied by

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Mr. Young." Tr. (McGavock) at 546:12-18. Mr. Young explained that for R&D expenditures on the rainbow® sensors, he relied on time allocations "received from our engineering leadership and teams," explaining that these allocations were "ranges anywhere from percent over time because that was a focus project for us." Tr. (Young) at 500:8-22. For manufacturing costs, Mr. Young explained that he relied on "the U.S. standard costs," which was pulled "from our financial data warehouse." *Id.* at 498:2-10. Mr. Young confirmed that the semiconductor LEDs for the rainbow® sensors are manufactured in Hudson, New Hampshire. *Id.* at 505:12-16, 507:7-15. He further confirmed that Masimo's engineering leads estimated that percent of the Laguna Canyon Road facility and percent of the Hudson facility was used to manufacture rainbow® sensors. *Id.* at 508:1-22. Although Masimo's estimates may not be precise, the record shows that Mr. McGavock and Mr. Young relied upon reasonable allocations of Masimo's expenditures to attribute the investments in plant and equipment to the rainbow® sensors.

There does not appear to be reliable support in the record, however, for Complainants' assertion that of Masimo's facility investments for rainbow® are domestic. See CIB at 310; Tr. (McGavock) at 549:8-14; CDX-0015C.017; RIB at 264-65; RRB at 163.

Mr. McGavock's testimony with respect to this figure is conclusory, with no explanation for how the percentage was calculated. See Tr. (McGavock) at 549:8-14; CDX-0015C.017.

Complainants cite two spreadsheets in their brief, see CIB at 310 (citing CX-0633C; CX-0636C), but it is not clear from these spreadsheets how the figure was derived. This is

Complainants' only basis for significance that relies on investments in plant and equipment, and because this figure is unreliable, Complainants have failed to show significant investment in plant and equipment under subparagraph (A) of section 337(a)(3).

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2. Labor or Capital

With respect to employment of labor or capital, Complainants rely on investments by Cercacor in research and development for the rainbow® sensors. CIB at 309.¹³¹ Complainants claim that "Cercacor has employed the to work on rainbow®." CIB at 299 (citing CDX-0015C.015 (summarizing CX-0633C)). As such, Complainants assert that Cercacor's expenditures in the employment of R&D labor or capital for the rainbow® sensors amounts to pre-2018 and from 2018-Q1 2021.

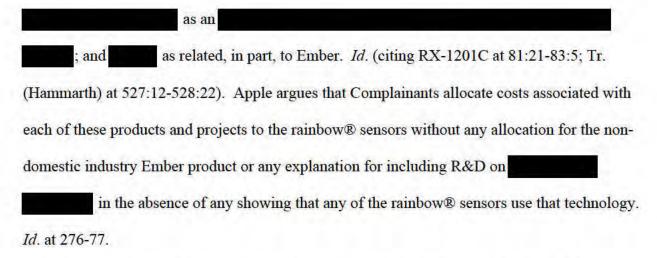
Id. at 309 (citing CX-0633C at "R&D Spend History" tab; CX-0644C). In addition, Complainants state that "Cercacor has performed the of its R&D on rainbow®, accounting for in R&D through July of 2021." Id. at 310 (citing Tr. (Hammarth) at 524:25-525:5).

Apple argues that Complainants offer no corroborating documentation for these R&D expenses or explain how their calculation provides a reliable basis for allocations necessary for the economic prong requirement. RIB at 276. In addition, Apple contends that Complainants fail to show that the R&D projects identified in Cercacor's R&D expenditures are exclusively related to the rainbow® sensors, rather than to non-domestic industry products and projects. *Id.* For example, Apple asserts that Complainants' expenditures include Ember, a commercialized product sold by Cercacor that is not a domestic industry product. *Id.* (citing Tr. (Hammarth) at 532:5-13). Similarly, Apple claims that Mr. Hammarth also identified as a

¹³¹ Complainants also set forth other labor or capital expenditures for the rainbow® sensors. *See* CIB at 309-10. However, because the other expenditures appear to be less reliable and are not as closely tied to Complainants' asserted bases for significance, only Cercacor's employment of R&D labor or capital is addressed herein.

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¹³² The undersigned finds that such evidence is reasonable under the circumstances of this investigation. As the Commission has stated, "there is no need to define or quantify the industry itself in absolute mathematical terms." *Certain Stringed Musical Instruments and Components Thereof*, Inv. No. 337-TA-586, Comm'n Op. at 26 (May 16, 2008) ("A precise accounting is not necessary, as most people do not document their daily affairs in contemplation of possible litigation.")

¹³³ Apple refers to exhibit CX-0633C and states that it "concerns Cercacor R&D Labor, with no apparent relevance." RRB at 163. Sworn testimony demonstrates that Cercacor developed the rainbow® technology, making Cercacor's investment in R&D labor related to rainbow®, *i.e.*, the subject of CX-0633C, relevant. *See* Tr. (Kiani) at 94:8-17, 119:9-12; Tr. (Hammarth) at 524:3-13.

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the financial spreadsheet prepared by Mr. Hammarth, as well as the financial spreadsheet prepared to support Mr. Young's declaration to the complaint. See CX-0633C; CX-0644C at Tab "Rainbow Chart" (showing that Cercacor's rainbow® R&D spend from 2007-2020 is about); Tr. (Young) at 488:2-17. And according to Mr. Hammarth all of that R&D "was done in the U.S." Tr. (Hammarth) at 525:6-8.

Moreover, the undersigned disagrees with Apple that certain R&D projects need to be excluded from Cercacor's R&D expenditures. The undersigned finds that a preponderance of the evidence shows that Cercacor specifically allocated certain of its projects to the rainbow® sensors. See, e.g., CX-0633 at Tab "Summary Calc" (showing subtotals for rainbow vs. non-rainbow). For example, Apple claims that the project is outside the scope of the rainbow® sensors. However, Mr. Hammarth testified that the and the rainbow® sensor measures a collection of nonvital signs, including and the rainbow® sensor measures a collection of nonvital signs, including and the rainbow at 528:1-6; see also id. at 528:23-529:2. Similarly, Mr. Hammarth testified that Ember is a Cercacor product that "incorporates our technologies for hemoglobin measurement, carbon monoxide measurement, and some others." Tr. (Hammarth) at 532:5-13; see also RX-1201C at 25:10-17 ("Ember is a small device that measures a number of blood constituents noninvasively."). The evidence, including documents

¹³⁴ As with the Masimo Watch, Complainants prepared several financial spreadsheets detailing their domestic expenditures for the rainbow® sensors. *See* CIB at 299-300. While Apple argues that these spreadsheets are unreliable as to the rainbow® sensors, Apple's arguments are unpersuasive for the same reasons as discussed above with respect to the Masimo Watch. *See* Part VII.C. *supra*.

See RX-1201C (Hammarth Dep.) at 82:2-4.

is the internal project name for the Ember product. See RX-1201C (Hammarth Dep.) at 82:8-10.